

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

CHEMIMAGE CORPORATION

Plaintiff,

v.

JOHNSON & JOHNSON and ETHICON, INC.

Defendants.

No.: 1:24-cv-2646 (JMF)

**PLAINTIFF CHEMIMAGE'S PROPOSED FINDINGS OF
FACT AND CONCLUSIONS OF LAW**

Andrew J. Rossman
Alex Spiro
Courtney C. Whang
Ron Hagiz

QUINN EMANUEL URQUHART &
SULLIVAN, LLP
295 5th Avenue
New York, New York 10016
(212) 849 7000

James Bieber

QUINN EMANUEL URQUHART &
SULLIVAN, LLP
865 S Figueroa Street, 10th Floor
Los Angeles, California 90017
(213) 443 3000

Attorneys for Plaintiff

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Plaintiff ChemImage Corporation, by and through its undersigned counsel, respectfully submits these Proposed Findings of Fact and Conclusions of Law pursuant to Rule 6(B)(iii) of the Court's Individual Rules and Practices in Civil Cases.

FINDINGS OF FACT

I. THE PARTIES

A. ChemImage

ChemImage Corporation ("ChemImage") is a Delaware Corporation headquartered in Pittsburgh.¹ Founded in 1994 by Dr. Patrick Treado, ChemImage develops multispectral imaging technology (*i.e.*, technology that captures images using different wavelengths of light) to detect materials that are not visible to the naked eye based on each material's unique molecular structure.²

While multispectral imaging has a wide range of potential uses, ChemImage's principal goal has been to develop an artificial intelligence-based ("AI") multispectral imaging platform that helps surgeons detect tumors and critical structures (*e.g.*, veins, arteries) during surgery that are obscured by tissue.³ Such technology can dramatically improve surgical outcomes by helping doctors avoid inadvertently damaging structures that are hidden under layers of fat or muscle.⁴

ChemImage's principal officers include Dr. Treado and Dr. Jeffrey Cohen. Dr. Treado currently serves as a consultant to ChemImage and is a member of the ChemImage Board of Directors, and at various times since its inception has served as ChemImage's President, Chief

¹ P. Treado Aff. ¶ 6.

² *Id.* ¶ 6.

³ *Id.* ¶ 7, 12.

⁴ *Id.* ¶ 7.

Technology Officer, and CEO.⁵ Dr. Treado holds a Ph.D. in Analytical Chemistry and is the inventor of over 190 patents primarily related to multispectral imaging and chemical imaging techniques.⁶ Dr. Cohen, ChemImage’s CEO, is a board certified urologic oncologist and surgeon who joined ChemImage in 2002.⁷ Prior to joining ChemImage, Dr. Cohen helped develop the first minimally invasive program for prostate cancer treatment.⁸ Dr. Cohen joined ChemImage because he believed, based on his experience in the operating room, that ChemImage’s technology could revolutionize surgery.⁹

In addition to Drs. Treado and Cohen, ChemImage retained a sophisticated team of doctors and scientists with experience in machine learning and AI to help develop its technology. In 2022, Dr. Adam Saltman, a decorated cardiothoracic surgeon with 25 years of clinical experience and over a decade at the FDA, joined ChemImage as Chief Medical Officer.¹⁰ Prior to ChemImage winding down, ChemImage’s staff consisted of over 70 employees, many of whom held advanced degrees, including master’s degrees and/or doctoral degrees in physical, medical, or computer science fields.¹¹

B. Johnson & Johnson

Johnson & Johnson (“J&J”) is a New Jersey-based multinational pharmaceutical, biotechnology, and medical technology company.¹² J&J, along with its subsidiaries, develops,

⁵ *Id.* ¶ 6.

⁶ *Id.* ¶ 4, 5.

⁷ J. Cohen Aff. ¶¶ 2-4.

⁸ *Id.* ¶ 3.

⁹ *Id.* ¶¶ 9-10.

¹⁰ A. Saltman Aff. ¶ 3.

¹¹ PDX-95 at 33 (ChemImage Corporation 2023 Business Plan); J. Cohen Aff. ¶ 40.

¹² PX-496 at 1 (J&J 10-K for the Fiscal Year Ended January 1, 2023).

manufactures, and sells a broad range of products in the healthcare field.¹³ By the end of 2023, after divesting its Consumer Health business, J&J was organized into two business units: Innovative Medicine and MedTech.¹⁴ J&J's MedTech division includes a portfolio of products used in Orthopedic, Surgery, Interventional Solutions, and Vision fields.¹⁵ In 2023, J&J's worldwide sales totaled approximately \$85.2 billion.¹⁶

C. Ethicon

Ethicon is a wholly-owned J&J subsidiary and part of J&J's MedTech division. Ethicon is responsible for developing and commercializing J&J's surgical intervention technologies.¹⁷

II. CHEMIMAGE PIONEERED MULTISPECTRAL IMAGING TECHNOLOGY

A. Multispectral Imaging And Machine Learning

ChemImage's imaging technology was designed to help surgeons visualize and detect structures in the body and cancerous tumors, even where those structures and tumors are not visible to the naked eye.¹⁸ To achieve this, ChemImage used multispectral imaging.¹⁹ In multispectral imaging, a surgical scene is sequentially illuminated by different wavelengths (colors) of light.²⁰ Different structures in the body have different spectral characteristics and will absorb and reflect

¹³ *Id.* at 7.

¹⁴ PX-872 at 7 (Johnson & Johnson 10-K for the Fiscal Year Ended December 31, 2023).

¹⁵ *Id.* at 8.

¹⁶ *Id.* at 29.

¹⁷ *Id.* at 8.

¹⁸ P. Treado Aff. ¶ 7; J. Cohen Aff. ¶ 12.

¹⁹ Some documents refer to ChemImage's technology as "hyperspectral imaging." Hyperspectral imaging and multispectral imaging operate under the same scientific principles; the main difference is in the number of different wavelengths of light that are used. "Multispectral" typically refers to applications using 1-10 different wavelengths, while "hyperspectral" refers to applications using more than 10 different wavelengths. The Project Erie technology was multispectral because it used 9 different wavelengths. P. Treado Aff. ¶ 14.

²⁰ P. Treado Aff. ¶ 14.

different wavelengths of light.²¹ By analyzing the scene when illuminated by each of the different wavelengths, critical structures within the scene (*e.g.*, veins, arteries, and bile ducts) can be identified based on their unique light absorption and reflection characteristics at each of the different wavelengths.²² ChemImage’s multispectral imaging technology used nine different wavelengths of light, carefully selected to include light that is uniquely absorbed by each of the critical structures of interest, as well as light that is uniquely absorbed by other structures in the body (*e.g.*, muscle, fat).²³

ChemImage used multispectral imaging to develop its two core technologies, **EndoVere** and **LightSphere**, each of which would act as a type of “night vision” for surgeons. Using different wave lengths and digital imaging, EndoVere would “reveal critical structures beyond the naked eye” and allow for “[a]ccurate tumor imaging in real time” (*i.e.*, during surgery).²⁴ This would greatly simplify critical structure and tumor identification during surgery and reduce physician error.²⁵ LightSphere, by contrast, is a diagnostic technology that similarly uses light wavelengths and digital imaging in order “to reveal, in real-time, cancerous and pre-cancerous tissue.”²⁶

To be effective in a surgical setting, imaging technology must be capable of recognizing multiple different critical structures (like arteries, veins, and bile ducts) simultaneously, including

²¹ *Id.* ¶ 12.

²² *Id.* ¶¶ 12-14.

²³ *Id.* ¶ 14.

²⁴ PX-149 at 2, 7 (Dec. 21, 2018 “ChemImage Strategic Partnering Overview” presentation).

²⁵ J. Cohen Aff. ¶ 12.

²⁶ PX-492 at 18 (Aug. 11, 2022 email attaching “ChemImage Overview” presentation, dated Aug. 10, 2022).

those that are obscured (*e.g.*, under layers of blood, tissue or fat).²⁷ To accomplish this, ChemImage’s technology utilizes **deep learning**, a type of artificial intelligence (“AI”) machine learning (“ML”) model that mimics neural networks in the human brain and enables the AI model to adapt the details of its operations based on prior input data, allowing it to “learn” and improve performance over time.²⁸ By using deep learning, an AI model can automatically “learn” spectral patterns that may be used to uniquely identify each critical structure and distinguish it from other “background” elements in the surgical scene.²⁹

Artificial intelligence, and deep learning in particular, is a particularly powerful tool to use when detecting and identifying critical structures and cancerous tissue because it can be trained to recognize and distinguish between different structures or “classes” in a dataset based on each class’s distinctive features.³⁰ Successfully utilizing AI requires training the algorithm or “model” with a dataset that contains examples of each class the AI model will be asked to identify.³¹ Once trained, an AI model can then identify patterns or combinations of features characteristic to each class and use that information to accurately identify the class present in any new data the AI model receives.³²

As an example (and as is relevant to this action), where an AI model’s goal is to identify certain critical structures (*e.g.*, arteries, veins, and bile ducts) present in a laparoscopic video image (*i.e.*, where a video recording is collected during a minimally invasive surgery conducted via laparoscopy), the AI model must first be trained using images where those critical structures have

²⁷ A. Saltman Aff. ¶ 17; D. Sodickson Aff. ¶¶ 37, 44.

²⁸ D. Sodickson Aff. ¶¶ 37, 43, 45-48.

²⁹ *Id.* ¶ 43.

³⁰ *Id.* ¶¶ 41-44; 53.

³¹ *Id.*

³² *Id.*; P. Treado Aff. ¶ 15.

already been successfully identified by a surgeon and labeled.³³ These labels, or annotations, on the training data are referred to as “**ground truth**” and act as an answer key from which the AI model learns.³⁴ Significantly, if erroneous data is used to train the model, such as by incorrectly labeling something a vein (when it is, in fact, something else), the model’s performance will be degraded (*e.g.*, it will learn to recognize things that are not veins as veins), and its output can become error-prone.³⁵ At the same time, the model must be trained on a sufficiently large volume of data to identify meaningful patterns that may be used to uniquely identify each critical structure under a range of conditions (different regions of the body, different degrees of obscuration, etc.).³⁶ Thus, training the AI model requires a careful balance of excluding potentially erroneous annotations, while ensuring that as much data as possible remains available for training.³⁷ An AI model may suffer *both* if the ground truth cannot be established with certainty *and* if large swaths of data are entirely excluded.³⁸

Just like in a real surgery, identifying critical structures under obscuration and adding “[p]ixel-level annotations [is] very challenging,”³⁹ and it is often not possible even for human surgeons and annotators to identify with certainty the ground truth of every pixel in a surgical image.⁴⁰ For example, a surgeon may positively identify a portion of an artery, but may still be uncertain of the entire length of the artery in the scene, particularly in portions where it branches,

³³ D. Sodickson Aff. ¶¶ 41-44; 53.

³⁴ *Id.*

³⁵ *Id.* ¶¶ 59, 113.

³⁶ D. Sodickson Aff. ¶ 55.

³⁷ *Id.* ¶¶ 55-57.

³⁸ *Id.* ¶¶ 55-57, 100-101.

³⁹ PX-251 at 16 (Feb 8, 2022 “Obscurations and Ground Truth Workstream” presentation prepared by Ethicon).

⁴⁰ A. Saltman Aff. ¶ 23; P. Treado Aff. ¶ 15.

is obscured under other tissue, or changes in depth. This is referred to as “uncertain ground truth.”⁴¹ In situations like this, where there is uncertainty about the underlying data, machine learning experts and data scientists frequently implement a process by which they add labels to portions of images that indicate to the network how to treat that uncertainty.⁴² Annotations instructing the model to ignore uncertain portions of a dataset are sometimes referred to as “uncertainty labels” or “**ignore labels**.”⁴³ “Ignore labels” can be configured to be treated differently by the AI model during training and evaluation. One possible treatment of labels to portions of an image where ground truth is uncertain is to instruct the model to “ignore” those uncertain pixels entirely during the training process.⁴⁴ Another approach, particularly when the surgeon has some confidence about the ground truth but is not entirely certain about whether a structure is in the field of view, is to “downweight” ignore labels during training, so that the data can still be used, but with less weight afforded to areas annotated with ignore labels in the model.⁴⁵ Using ignore labels on images where there is some uncertainty in portions of the image, but ground truth can be established with certainty in other portions of the image, is preferable to excluding those images entirely.⁴⁶ This is especially true when working with a smaller dataset because it preserves as much good data as possible, while excluding data with uncertain ground truth.⁴⁷

⁴¹ A. Saltman Aff. ¶¶ 23, 31.

⁴² D. Sodickson Aff. ¶¶ 58-61.

⁴³ D. Sodickson Aff. ¶ 61.

⁴⁴ See PX-462 at 5-8 (Mar. 8, 2021 email attaching “Labelling Strategy” presentation prepared by Cambridge Consultants).

⁴⁵ D. Sodickson Aff. ¶ 61.

⁴⁶ *Id.* ¶¶ 119-120.

⁴⁷ *Id.* ¶¶ 94, 119-120.

In operation, ChemImage’s trained AI model would work by processing multispectral images of a surgical scene and generating visual depictions of detected critical structures.⁴⁸ An image of the surgical scene illuminated under each wavelength of light would be captured by an endoscope (a small tool inserted into an incision in the body) that would be developed and supplied by J&J and Ethicon.⁴⁹ The AI model would then process the spectral information from those images and generate probabilities for each pixel in the scene, predicting the likelihood that each pixel is a vein, artery, bile duct, or “background” (*i.e.*, none of the above).⁵⁰ The predictions would then be processed by another layer of software that visualizes and overlays them onto an image of the surgical scene, shown on a display, so that an operating surgeon could see the detected critical structures in near-real time.⁵¹

III. J&J SOUGHT OUT CHEMIMAGE TO BOLSTER ITS SURGICAL ROBOTICS PROGRAM

Despite its early success commercializing EndoVere for use outside of the medical field (*e.g.*, detecting contraband and explosives for the government),⁵² ChemImage recognized the benefit of working with a large, strategic partner that could help integrate and distribute ChemImage’s technology with surgical devices.⁵³ Between 2013 and 2018, ChemImage entertained a number of potential partners, including Intuitive Surgical, Inc. (“Intuitive”), Hitachi, Stryker, Siemens, and Medtronic.⁵⁴

⁴⁸ P. Treado Aff. ¶¶ 15-16.

⁴⁹ PX-1 at 58 (Dec. 27, 2019 Research, Development, License and Commercialization Agreement) (the “Agreement”).

⁵⁰ D. Sodickson Aff. ¶¶ 41-43, 69.

⁵¹ P. Treado Aff. ¶ 16; *see also* PX-22 at 31-33 (Nov. 17, 2022 “Erie Program EL9 Test Readiness Review” presentation).

⁵² J. Cohen Aff. ¶ 16.

⁵³ J. Cohen Aff. ¶ 19.

⁵⁴ J. Cohen Aff. ¶¶ 20-21.

When ChemImage advisor (and former President of Ethicon), Gary Pruden, introduced ChemImage to personnel from J&J, ChemImage believed that they had found the right partner.⁵⁵ J&J enthusiastically pursued ChemImage. After receiving a demonstration of ChemImage's technology at one of the parties' initial meetings, Sarah Moore, Ethicon's Marketing Director for Digital Surgery & Advanced Imaging, told Dr. Cohen that J&J had been "*searching for a company like ChemImage*" for a decade.⁵⁶

Around the same time, J&J was actively developing a robotics platform that it hoped would allow it to compete with Intuitive, the industry leader in surgical robotics.⁵⁷ In 2019, J&J acquired the remainder of its partial stake in Verb Surgical ("Verb"), a surgical robotics company previously owned by Verily, a subsidiary of Google's parent company.⁵⁸ In 2019, J&J also acquired Auris Health, Inc. ("Auris"), which was developing its own surgical robotics platform intended to rival market-leader, Intuitive.⁵⁹

As a late entrant to the surgical robotics field, J&J knew that its surgical robotics platforms needed to differentiate from competitor's products (*i.e.*, perform better and offer additional desirable features), and ChemImage offered it the opportunity to do just that.⁶⁰ Defendants

⁵⁵ J. Cohen Aff. ¶ 22.

⁵⁶ J. Cohen Aff. ¶ 23 (emphasis added).

⁵⁷ See, e.g., PX-500 at 3-9 ("Erie December Competitive Connection" presentation, prepared by J&J); PX-501 at 11 (Jan. 24, 2020 email attaching "Project Jupiter Statement of Work") (describing a statement of work for "pre-development of a 3D endoscope for robot-assisted surgery"); see also PX-5 (Press Release, "Johnson & Johnson Announces Formation of Verb Surgical Inc., In Collaboration With Verily").

⁵⁸ See PX-6 (Press Release, "Johnson & Johnson Announces Agreement to Acquire Remaining Stake in Verb Surgical Inc.").

⁵⁹ See PX-7 (Press Release, "Johnson & Johnson Announces Agreement to Acquire Auris Health, Inc.").

⁶⁰ PX-497 at 11 (Dec. 24, 2019 "Advanced Imaging/Project Erie – Request for Approval of Final Negotiated Deal Terms" presentation, prepared by J&J) ("Competitor acquisition of Erie provides Advanced Imaging head start in robotics (esp. for [Intuitive Surgical] da VinciTM and IONTM)"); see also P. Ritchie Dep. Tr. at 20:21-21:1 ("Q. ... So is it fair to say that ... at the time the agreement was entered into,

recognized that partnering with ChemImage would give them a “strong competitive advantage” in surgical robotics and access to technology that was “~3 years ahead of the competition,” including because ChemImage had the only multispectral technology in development “with versatility to detect multiple structures & cancers.”⁶¹ Although J&J “explored alternatives in hyperspectral [imaging] ... and plan B technologies,” it concluded that “ChemImage was [its] best option for a solution in the near term.”⁶²

Internally, J&J and Ethicon touted ChemImage’s “potential to provide transformational advanced imaging capability for improved decision-making and efficiency in robotic-assisted laparoscopic & endoluminal as well as traditional MIS [minimally invasive] surgery.”⁶³ In 2018, J&J projected peak annual revenue from a partnership with ChemImage to be up to \$340 million per year.⁶⁴ Four years later—and just nine months *before* purportedly terminating the Agreement “for cause”—Defendants would observe that their partnership with ChemImage actually represented “a significantly *larger* revenue opportunity in the non-robotic laparoscopic visualization market” than previously forecasted, estimating “a \$1.1B peak year forecast vs \$0.4B in the 2019 deal model.”⁶⁵

Ethicon and ChemImage were trying to use hyperspectral imaging technology in a novel way? A. I would agree with that[, with respect to critical structures]”).

⁶¹ PX-497 at 2.

⁶² PX-307 at 8 (June 24, 2022 “Erie Program Technical Review – Peter Shen”).

⁶³ PX-497 at 2.

⁶⁴ *See id.* at 2, 3, 6; *see also* PX-502 at 5 (June 24, 2022 “Erie Program Technical Review – Peter Shen” presentation) (“We saw enough data and expertise [from ChemImage] to engage in a joint feasibility agreement.”).

⁶⁵ PX-321 at 3 (June 17, 2022 “Project Erie – Amendment of Development Agreement with ChemImage Corp. – Review with Susan Morano & Kurt Van den Bosch” presentation).

J&J also knew that forgoing the opportunity to partner with ChemImage posed its own risks.⁶⁶ An August 2018 presentation on Ethicon’s “Digital Surgery Pipeline” stated that “[e]ven if [ChemImage’s] technology is unsuccessful, *investing enough through 2020 to complete pre-charter diligence is better financial risk than losing [ChemImage] to a competitor* given lack of readily available or known substitutes.”⁶⁷ An internal memorandum addressed to J&J executives, including J&J’s then-worldwide CEO, Alex Gorsky, acknowledged the risk to J&J if the parties’ did not partner: “[i]f [the] deal is not attainable,” there would be “*significant risk* to [J&J’s] committed digital surgery strat[egic] plan.”⁶⁸

By June 2019, J&J’s executive team gave the final approval to move ahead with a deal with ChemImage.⁶⁹ J&J declared ChemImage a “Key Project[]” that would serve as “a critical piece of the advance imaging digital surgery platform with additional utility in traditional laparoscopy.”⁷⁰ Although ChemImage was engaged in talks with other potential partners and had also received a term sheet from Medtronic,⁷¹ ChemImage ultimately chose to partner with J&J and

⁶⁶ See PX-324 at 19 (Feb 8, 2022 email attaching “May 6, 2019 Advanced Imaging/Project Erie – Alignment on Approval of Non-Binding Offer” presentation) (recognizing that a “[c]ompetitor acquisition of Erie would provide an Advanced Imaging head start in robotics” and pose a “potential >\$500M risk to committed Digital surgery forecast” for J&J); see also PX-326 at 16 (Jan. 11, 2021 email attaching “Advanced Imaging/Project Erie – Request for Approval of Final Negotiated Deal Terms” presentation) (“Erie technology is uniquely positioned within the Ethicon Advanced Imaging Portfolio due to its potential ability to detect and visualize multiple key critical structures ... Without the Advanced Imaging portfolio, the competitiveness of the JNJ Robot to win contracts vs. ISRG and MDT is reduced, given competitors are also investing in Advanced Imaging.”).

⁶⁷ PX-782 at 27 (Aug. 2, 2018 “Ethicon Digital Surgery Pipeline Overview” presentation) (emphasis added); see also T. Lanier Dep. Tr. at 64:11-15 (stating that, with respect to PX-782, “Ethicon believed that the potential represented by the ChemImage technology would allow us to develop and deliver against the critical unmet needs that we were trying to solve for in our portfolio.”).

⁶⁸ PX-326 at 3 (Jan. 11, 2021 email attaching “Advanced Imaging/Project Erie – Request for Approval of Final Negotiated Deal Terms” presentation).

⁶⁹ PX-399 at 8 (June 19, 2019 “Deal Committee Monthly Update” presentation, prepared by J&J); see also P. Treado Aff. ¶ 22.

⁷⁰ PX-399 at 18.

⁷¹ J. Cohen Aff. ¶ 28.

Ethicon based on J&J’s favorable contract language (*e.g.*, a \$40 million termination fee), and perceived strategic alignment.⁷²

IV. THE DEFINITIVE AGREEMENT

A. The Parties Execute The Agreement

After months of negotiations, the parties entered into the Research, Development, License, and Commercialization Agreement (the “Agreement”) on December 27, 2019.⁷³ Under the Agreement, Ethicon agreed to pay ChemImage up to \$174 million, including \$7 million upfront and \$149 million in potential milestone payments.⁷⁴ In turn, ChemImage granted Ethicon an exclusive license to the “CI Core IP in the Endovere Field,” and a non-exclusive license to the “CI Core IP and CI Developed Lightsphere IP in the Lightsphere Field.”⁷⁵ The parties’ work under the Agreement was referred to as “**Project Erie**” or the “Erie Program.”⁷⁶

With respect to EndoVere, these provisions granted Ethicon an exclusive license to all intellectual property (“IP”) that ChemImage developed before or independent of the Agreement with applications directed to surgical detection, visualization, and identification of anatomic structures, as well as tumor detection (“CI Core Endovere IP”).⁷⁷ With respect to Lightsphere, these provisions granted Ethicon a non-exclusive license to all IP that ChemImage developed

⁷² PX-435 at 5-6, 139.

⁷³ *See* Agreement.

⁷⁴ Agreement § 3.1; Ex. B.

⁷⁵ *Id.* §§ 4.1.1; 4.1.2.

⁷⁶ *See* P. Treado Aff. ¶ 22; P. Ritchie Dep. Tr. 23:20-22 (“Project Erie was the internal code name that was given to [Defendants’] program with ChemImage.”).

⁷⁷ Agreement §§ 4.1.1; 1.

before, independent of, and during the Agreement with applications related to tumor diagnosis (“CI Core LightSphere IP”).⁷⁸

B. Development Plan and Milestones

In Agreement Section 2.1, the parties agreed to a “Development Plan” that defines the scope of work under the Agreement.⁷⁹ The Development Plan was attached as Exhibit A to the Agreement, and includes *no dates* by which any task was to be achieved, and states “further details and timeline of the Development Plan to be updated at the kick-off and JSC meetings” and “[j]oint planning is required ... to ensure the creation of a comprehensive plan.”⁸⁰

The parties agreed to six “Development Milestones” and six “Regulatory Milestones” (together, the “Milestones”).⁸¹ The “Development Milestones” were tied to achievement of certain technical steps, while the “Regulatory Milestones” were tied to obtaining FDA approval of products incorporating ChemImage’s technology.⁸² Notably, the Agreement prescribed no fixed deadlines by which ChemImage was required to achieve any of the Milestones or specific research and development tasks.⁸³ Instead, it set out a range of target dates for certain research and development tasks and “anticipated invoice date[s]” to be paid by Ethicon for “Major R&D tasks.”⁸⁴ Flexibility and “joint planning” was built into the Agreement with respect to the timing of Milestone achievement because the parties were developing a novel technology that would be

⁷⁸ *Id.* §§ 4.1.2; 1.

⁷⁹ *Id.* § 2.1.

⁸⁰ *Id.*, Ex. A at 54.

⁸¹ *Id.*, Ex. B at 56-58.

⁸² *Id.*

⁸³ *Id.* at 55-58; *see also* P. Ritchie Dep. Tr. at 40:9-14 (“Q. ... Is it your understanding that the dates listed in the chart are firm dates that had to be met unless it was agreed to otherwise that they could be moved? A. I don't know that I would say they were firm dates that had to be met ...”).

⁸⁴ Agreement, Ex. B at 55.

applied in a novel way.⁸⁵ Importantly, Ethicon’s then-director of Advanced Visualization, Paul Ritchie, who was involved in Ethicon’s decision to partner with ChemImage,⁸⁶ served as an Ethicon JSC representative, and oversaw the partnership, admitted there were no fixed dates by which ChemImage needed to achieve any of the Milestones in the Agreement.⁸⁷ Mr. Ritchie further admitted that Ethicon could not unilaterally impose a Milestone achievement timeline on ChemImage.⁸⁸

Each Development Milestone required ChemImage to demonstrate different technological capabilities.⁸⁹ However, the Development Milestones could not be achieved by ChemImage alone; they required participation from Defendants. For example, in order to achieve Milestone 1B (“M1B”), ChemImage was required to conduct a “successful in-vivo demonstration” using “a prototype *J&J/Ethicon Visualization System* of Critical Structure Identification Functionality” that Defendants had to provide.⁹⁰ In other words, M1B required pairing ChemImage’s software with hardware developed by J&J and Ethicon. This hardware, referred to internally by J&J and Ethicon as “Athena,” was still in development after the parties entered into the Agreement.⁹¹

⁸⁵ P. Ritchie Dep. Tr. 21:2-8; J. Cohen Aff. ¶ 33; P. Treado Aff. ¶ 23; A. Saltman Aff. ¶ 10.

⁸⁶ P. Ritchie Dep. Tr. at 11:21-12:21 (testifying that he was “involved with ChemImage” in 2018, when Ethicon “completed a small pilot program with [ChemImage] that then led to [Defendants] entering in[to] a contract in 2019”); *id.* at 17:23-18:10 (explaining that Ethicon “decided to work with ChemImage” so that it could “integrate[]” ChemImage’s technology into “a feature on [a] laparoscopic visualization system” Ethicon was planning to market).

⁸⁷ *Id.* at 48:8-49:5.

⁸⁸ *Id.* at 41:2-22.

⁸⁹ Agreement, Ex. B at 59-69.

⁹⁰ *Id.* at 62.

⁹¹ PX-503 at 4 (Dec. 11, 2020 “Project Athena Co-Development Needs” presentation); *see also* PX-504 (“ChemImage Description of the 2023 R&D Feasibility Program” prepared by Rich Gooding) (“2023 Program ... EP [Erie Program] aligning with Athena HW [hardware] availability”); P. Ritchie Dep. Tr. at 108:23-25 (“Q. And ChemImage’s hyperspectral imaging technology, that was going to be used on Athena? A. That’s correct.”); PX-193 at 9 (Jan 12, 2021 JSC Meeting Presentation) (Defendants’

Accordingly, ChemImage could not even attempt M1B unless and until Defendants provided functional hardware with the correct visualization capabilities.⁹² Further, Defendants required ChemImage to conduct all data collection at J&J facilities in Blue Ash, NC on live porcine (pig) subjects.⁹³

In addition to providing the hardware for M1B, Defendants were required to make regular payments for research and development tasks and to meet certain deadlines, including a “Launch Deadline,” (*i.e.*, the deadline by which Ethicon was required to make its First Commercial Sale).⁹⁴

C. The Joint Steering Committee (“JSC”)

The Agreement required that the parties establish a joint steering committee (“JSC”) to govern the parties’ efforts under the Agreement.⁹⁵ The JSC was a four-person committee comprised of two individuals authorized to make decisions about Project Erie for ChemImage and Ethicon, respectively. JSC meetings were to be held “no less frequently than once in each six (6) month period” and at either Party’s request.⁹⁶

Per the Agreement, the JSC’s responsibilities included: (1) “adjust[ing] the Development Timeline, Milestones and the Launch Deadline, as necessary in its sole discretion, to further the goals of the Development Program;” (2) “determin[ing] whether the Milestones specified in Exhibit B have been met;” (3) “consider[ing], review[ing], reevaluat[ing] and discuss[ing] the

“Advanced-Imaging-enabled Visualization System will be known ‘Athena,’” which “includes the laparoscopes, control unit, and our initially-launched use cases. ... We will continue to refer to our partnership as ‘Erie’, and the use cases you are developing will eventually be integrated and launched on the ‘Athena’ system.”).

⁹² P. Treado Aff. ¶ 31; *see also* PX-505 at 2, 3 (Nov. 24, 2020 “Erie – Sponsor Dashboard” presentation) (showing Athena Milestones needed to be reached before Erie M1B).

⁹³ A. Saltman Aff. ¶ 14.

⁹⁴ *See* Agreement § 10.2.2(b), Ex. B at 55.

⁹⁵ *See* Agreement § 2.4.

⁹⁶ *Id.* § 2.4.2; P. Treado Aff. ¶¶ 24-25.

Development Plan;” and (4) “consider[ing] modifications to the Development Plan (including adjustments to the Development Timeline) proposed by either Party.”⁹⁷

Significantly, the JSC is the *only mechanism* by which the parties could “determine whether the Milestones” had been met.⁹⁸ The Agreement makes no other reference to a process for determining Milestone achievement, other than the JSC.⁹⁹ Mr. Ritchie, Ethicon’s JSC representative and partnership lead, confirmed that “neither party could unilaterally determine whether a Milestone was met.”¹⁰⁰ Consistent with Mr. Ritchie’s admission, the Agreement required that all JSC decisions be “made by unanimous vote,” with ChemImage and Ethicon members each receiving one vote per party.¹⁰¹ In the event a unanimous decision could not be reached, the Agreement outlined a specific process for breaking a deadlock.¹⁰² Specifically, the Agreement stated that,

In the event a deadlock occurs with respect to a modification of the Development Plan, the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions. In the case of a JSC deadlock after such period, the issue will be escalated to the Head of Digital Surgery of Company and to the Chief Executive Officer of CI for resolution for a period of fifteen (15) days. If the issue cannot be resolved after such combined forty-five (45) day period, either Party may refer the unresolved matter for binding arbitration pursuant to Section 12.9 of this Agreement.¹⁰³

D. Termination Provisions

⁹⁷ Agreement § 2.4.

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ P. Ritchie Dep. Tr. 41:23-42:17.

¹⁰¹ Agreement § 2.4.3.

¹⁰² See PX-502 at 5 (describing the work of the JSC to be *inter alia* “[o]versee[ing] milestones” and to “resolve deadlocks”).

¹⁰³ Agreement § 2.4.3(b).

Both parties were permitted to terminate the Agreement, subject to the specific conditions in the Agreement.

1. Termination By Ethicon For Cause Required Failure To Achieve A Development Milestone

Ethicon was permitted to terminate the Agreement “for cause” if and only if ChemImage materially breached the Agreement by failing to meet a Development Milestone.¹⁰⁴ Specifically, Section 10.3.1 provides: “[Ethicon] may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event [ChemImage] shall have materially breached or defaulted in the performance of any of its *obligations hereunder*.”¹⁰⁵ The section that follows (*i.e.*, the obligations “hereunder”) identifies *only one event*, “should [it] occur, [that] shall constitute a CI material breach.”¹⁰⁶ That *singular* event is defined, in its entirety, as “[ChemImage’s] failure, subject to the cure provisions of Section 10.3.1, to achieve a Development Milestone as described in Exhibit B.”¹⁰⁷

The Agreement also provides that, if ChemImage failed to achieve a Development Milestone, Ethicon would need to provide ChemImage with “a written notice” that “specifies *in reasonable detail* the nature of the breach or default, states that [ChemImage] is required to cure such breach or default and states that failure to cure such breach or default will result in termination of this Agreement.”¹⁰⁸ ChemImage then would have 30 days to cure the breach.¹⁰⁹

¹⁰⁴ See generally Agreement §§ 10.3.1; 10.3.2.

¹⁰⁵ Agreement § 10.3.1 (emphasis added).

¹⁰⁶ Agreement § 10.3.2.

¹⁰⁷ Agreement § 10.3.2 (a).

¹⁰⁸ Agreement § 10.3.1 (emphasis added).

¹⁰⁹ Agreement § 10.3.1.

Critically, if ChemImage’s breach or default was “not reasonably capable of being cured within such 30-day period, termination shall *not be effective* if CI commences cure of the breach or default within such 30-day period and thereafter diligently prosecutes such cure to completion.”¹¹⁰

If Ethicon properly terminated the Agreement “for cause,” all IP rights reverted to the owner of the applicable IP, and ChemImage was required to grant Ethicon (i) an *exclusive*, assignable license to the CI Core IP, and (ii) a non-exclusive, assignable license to the CI Developed Lightsphere IP.¹¹¹ In other words, upon a for cause termination, Ethicon would continue to hold exclusive rights to all IP that ChemImage developed before or independent of the Agreement with applications directed to surgical detection, visualization, and identification of anatomic structures, as well as tumor detection.¹¹²

2. Termination By Ethicon Without Cause Required A \$40 Million Termination Fee

Absent ChemImage’s failure to meet a development Milestone, Ethicon also had the option to terminate the Agreement “without cause.”¹¹³ If Ethicon terminated the Agreement “without

¹¹⁰ Agreement § 10.3.1.

¹¹¹ Agreement § 10.3.3. Section 2.4 of the Agreement defines the following relevant intellectual property assets owned by each party and to be developed over the course of the Agreement, including:

“**CI Core IP**” refers to (1) all IP Controlled by ChemImage before the Agreement was executed, or (2) IP unrelated to Project Erie that was developed by ChemImage after the Agreement was executed and without using funds paid by Defendants to ChemImage under the Agreement;

“**CI Developed Lightsphere IP**” refers to IP developed by ChemImage under the Agreement that can be used in the Lightsphere Field and not in the EndoVere Field;

“**CI Developed EndoVere IP**” refers to IP developed by ChemImage under the Agreement that can be used in the EndoVere Field (but excluding CI-developed Intellectual Property directed solely to Lightsphere Field); and

“**Collaboration IP**” refers to all IP developed jointly by CI and Ethicon pursuant to the Agreement.

¹¹² Agreement §§ 4.1.1; 1.

¹¹³ Agreement § 10.4.

Cause,” it was required to pay ChemImage a \$40 million termination fee and provide ChemImage with 120-day notice prior to termination.¹¹⁴

Additionally, if Ethicon terminated the Agreement “without cause,” all IP rights (including the ChemImage Core IP) would *revert to the owner* of the applicable IP, and Ethicon would grant ChemImage royalty-free, non-exclusive licenses to the Collaboration IP and CI Developed EndoVere IP, as well as a non-exclusive license to certain intangible know-how from the Collaboration IP, the CI Developed EndoVere IP, and Ethicon’s own IP.¹¹⁵ In other words, in the event that Ethicon terminated the Agreement without cause, ChemImage would regain full rights to all IP that ChemImage developed before or independent of the Agreement with applications directed to surgical detection, visualization, and identification of anatomic structures, as well as tumor detection.¹¹⁶

The \$40 million termination fee was put in place to ensure that ChemImage had the funding necessary to find a new potential partner in the event Ethicon terminated the Agreement without cause.¹¹⁷ ChemImage insisted on the \$40 million termination fee at the advice of ChemImage advisor, Aileen Stockburger, who was also J&J’s former Worldwide Vice President, Business Development.¹¹⁸ Specifically, Ms. Stockburger informed Dr. Cohen that, based on her experience at J&J, ChemImage should insist on a breakup fee.¹¹⁹ ChemImage heeded Ms. Stockburger’s advice.

V. PROJECT ERIE

¹¹⁴ Agreement § 10.4.

¹¹⁵ Agreement § 10.4.4.

¹¹⁶ Agreement §§ 4.1.1, 1.

¹¹⁷ See J. Cohen Aff. ¶ 32.

¹¹⁸ J. Cohen Aff. ¶ 32; P. Treado Aff. ¶ 10.

¹¹⁹ J. Cohen Aff. ¶ 32.

A. ChemImage Achieves Milestone 1A

Almost immediately after the Agreement was executed, Project Erie suffered delays due to the COVID-19 pandemic. While the pandemic was at its height, J&J closed its testing facility at Blue Ash where the surgical labs were conducted to generate data and images used to train ChemImage's AI model.¹²⁰

Nevertheless, ChemImage was able to quickly achieve Milestone 1A ("M1A") by October 30, 2020.¹²¹ The objective of M1A was to demonstrate the detection abilities of ChemImage's technology for the real-time detection of critical structure targets, using ChemImage's own hardware.¹²² The parties completed the following steps to determine whether M1A was met:

- *First*, the JSC agreed to "acceptance criteria" for M1A that were based on the M1A criteria set forth in the Agreement;
- *Second*, ChemImage submitted a draft and a Final Report for M1A ("M1A Final Report") to the JSC for approval;
- *Third*, Ethicon and its consultant, Cambridge Consultants ("Cambridge"), reviewed the M1A Final Report;
- *Fourth*, the JSC was convened to review the M1A Final Report, where it voted unanimously that ChemImage had met the requirements of M1A.
- *Fifth*, Ethicon made the required \$5,000,000 M1A payment to ChemImage.¹²³

¹²⁰ J. Cohen Aff. ¶ 42.

¹²¹ PX-118 at 3 (Nov. 6, 2020 appointment attaching "JSC Meeting 10 Minutes," dated Oct. 30, 2020).

¹²² See Agreement, Ex. B at 60-62; P. Ritchie Dep. Tr. at 103:18-23 ("Q. ... you said it was a pretty big difference -- is that the Milestone 1a involved a demonstration on ChemImage's platform, and Milestone 1b involved pairing ChemImage's technology with hardware developed by Ethicon; is that right? A. Correct.").

¹²³ See PX-174 (Oct. 30, 2020 email from M. Steich); P. Ritchie Dep. Tr. 61:1-63:2, 63:20-64:14 ("Q. ... So with respect to Milestone 1A, the JSC agreed to a milestone acceptance criteria, ChemImage submitted final and draft reports. Then those reports were reviewed by Cambridge and Ethicon. And then Milestone 1a was approved by the JSC. Do I have that right? ... A. Those are the steps that I recall taking place. There was -- after the review by the JSC and before the final approval, there were other discussions about some of the perceived shortcomings of that work.").

B. Defendants Delay Project Erie and Achievement of M1B

Following completion of M1A, ChemImage began working in earnest towards achieving M1B, which required successfully pairing ChemImage software with hardware developed by Ethicon.¹²⁴ Despite ChemImage's best efforts, progress towards achieving M1B was delayed due to internal issues at Ethicon and Ethicon's failure to develop the required hardware.

1. Ethicon Lacked Technical Proficiency

Ethicon's Project Erie Program Coordinator, Paul Ritchie, admitted that Ethicon lacked any in-house expertise to develop its own hyperspectral imaging platform similar to ChemImage's.¹²⁵ Mr. Ritchie also admitted that Ethicon had *no* employees that specialized in hyperspectral imaging, and could not identify anything Ethicon did during the course of Project Erie to increase its expertise in this area.¹²⁶

Because Ethicon lacked the requisite in-house experience to understand the nuances of ChemImage's technology, Defendants enlisted two external, technical consultants: Cambridge and Kitware.¹²⁷

Cambridge was initially hired by Defendants to perform technology reviews of Project Erie and the technological landscape, and was eventually retained as Defendants' data reviewer for

¹²⁴ Agreement, Ex. B at 8-9.

¹²⁵ PX-683 (Feb. 13, 2020 Erie Program Task 2.1.2 – Critical Structure (CS) ex vivo TRR Meeting presentation). *See, e.g., id.* at 10-11 (showing risks anticipated by the parties at the onset of the program); P. Ritchie Dep. Tr. at 36:10-15 (“Q. Okay. In your understanding, when the agreement was entered into, Ethicon did not have the expertise to develop a hyperspectral imaging platform in house; is that right? A. I think that’s correct.”).

¹²⁶ PX-683 at 10-11; *see also*, P. Ritchie Dep. Tr. at 21:25-22:11 (testifying that Ethicon had no employees that specialized in hyperspectral imaging); *see also id.* at 22:8-11 (“Q. From 2020 to 2023, can you identify anyone at Ethicon hired who had experience working on a hyperspectral imaging platform? A. No.”).

¹²⁷ PX-567 (October 19, 2021 email from E. Osmanagic); PX-174 at 4.

Project Erie from May 2020 until 2023.¹²⁸ As part of its work—which included reviewing ChemImage’s data and weekly discussions with Ethicon about that data¹²⁹—Cambridge concluded that “ChemImage is a data-driven, evidence-based and transparent organization and this gives us good confidence in the underlying data supporting their claims.”¹³⁰

Defendants also hired Kitware, a company specializing in software development, to help evaluate ChemImage’s algorithm framework.¹³¹ Kitware served as Ethicon’s in-house algorithm team, which was otherwise nonexistent.¹³²

Notably, Ethicon’s key technical manager on Project Erie, Tarik Yardibi, commented that “We (ETH) spend a lot of money with organizations like Kitware & Cambridge Consultants. They charge top dollar for their services and *CI is as good or better than they are.*”¹³³ Mr. Yardibi confirmed that “ChemImage’s team is world-class experts in the Algorithm Realm.”¹³⁴ Consistent with Mr. Yardibi’s assessment, Heather Gomer, ChemImage’s then-Director of Algorithms, confirmed that although Kitware was hired to help with algorithms, it ultimately did not assist ChemImage with anything.¹³⁵

¹²⁸ See PX-438 at 18 (June 12, 2023 “Project Erie – Our Engagement” presentation prepared by Cambridge Consultants).

¹²⁹ See e.g., PX-378 (Oct. 5, 2022 Weekly Cambridge Algorithm Analysis Call video recording); PX-552 (Feb. 22, 2021 Zoom invitation from L. Glover); PX-553 (Nov. 17, 2020 Zoom invitation from L. Glover).

¹³⁰ PX-470 at 31 (Oct. 2020 “Erie Milestone 1A Summary Report” prepared by Cambridge Consultants); see also, PX-554 (Apr. 7, 2020 email attaching “Assess Matrix Sept 2018 Cambridge” spreadsheet prepared by Cambridge Consultants).

¹³¹ PX-555 (May 13, 2021 appointment from V. Clifford for Kitware Kickoff Meeting).

¹³² See PX-307 at 42 (June 24, 2022 email attaching “Erie Program Technical Review” presentation, dated June 24, 2022).

¹³³ PX-561 at 1 (Jan. 26, 2022 email from R. Ghosh) (emphasis added).

¹³⁴ PX-870 at 4 (Jan. 25, 2022 email attaching “JSC 2022 Meeting 1 – Meeting Minutes”, dated Jan. 25, 2022).

¹³⁵ See H. Gomer Dep Tr. at 74:9-21 (“[Kitware] did not assist [ChemImage] with algorithm development ... I don’t think [Kitware] assisted [ChemImage] with anything, in my opinion”).

Ethicon’s lack of in-house technical expertise hampered its ability to communicate with ChemImage on a technical level, instead routing most technical discussions through its outside consultants.¹³⁶ This disjointed communication often strained the parties’ working relationship.¹³⁷ To make matters worse, there was frequent turnover at Ethicon. From 2021 to 2022, the first voting JSC members from Ethicon, Sarah Moore (Marketing Director for Digital Surgery & Advanced Imaging)¹³⁸ and Paul Ritchie (Director of Advanced Visualization R&D),¹³⁹ were replaced, respectively, by Tamara Lanier (then-Global Marketing Innovation & Pipeline Leader)¹⁴⁰ and Francesc Fernandez (VP of R&D).¹⁴¹ Mr. Fernandez also replaced Mr. Ritchie as the Ethicon Program Coordinator for Project Erie.¹⁴² These changes also contributed to delay, as later decisionmakers were not up to speed on project design nor did they understand the nuances of ChemImage’s technology.¹⁴³

2. Ethicon’s Hardware Development Was Significantly Delayed

While ChemImage was making strides with its software, Defendants’ development of Project Erie hardware, “Athena”¹⁴⁴, was significantly delayed.

¹³⁶ P. Treado Aff. ¶¶ 26, 60.

¹³⁷ P. Treado Aff. ¶¶ 26, 60, 62.

¹³⁸ PX-506 at 1 (Jan. 4, 2020 email from N. Hristovska).

¹³⁹ See PX-347 at 4 (Mar. 3, 2020 JSC Meeting 2 presentation); P. Ritchie Dep. Tr. 8:4-22; P. Ritchie Dep. Tr. 33:16-18.

¹⁴⁰ See PX-206 at 3 (Apr. 13, 2021 JSC Meeting 4 presentation).

¹⁴¹ PX-195 at 2 (Jan. 25, 2022 JSC Meeting 1 presentation).

¹⁴² See PX-40 at 4 (June 27, 2022 email attaching “Joint Steering Committee (JSC) 2022 Meeting 6” presentation, dated June 28, 2022).

¹⁴³ P. Treado Aff. ¶ 26; J. Cohen Aff. ¶ 44.

¹⁴⁴ See PX-735 at 22 (Nov. 15, 2021 appointment attaching “Erie Program Timeline Deliverable Analysis”, dated Jan. 9, 2022).

Not long into the Agreement, Athena's development was already significantly behind schedule and impacting the Project.¹⁴⁵ In mid-2021, as a result of Athena delays, **Ethicon** proposed a 12 month extension to the Project Erie product "Launch Deadline" that Ethicon was required to meet under the Agreement.¹⁴⁶ In July 2021, Emir Osmanagic, told Paul Ritchie that Ethicon needed help with Project Erie because Defendants' Athena hardware was "still very unstable, preventing [the] team [from] advanc[ing its] work."¹⁴⁷ Mr. Osmanagic further complained that he felt that Project Erie was not "getting [the] priority and attention that's needed [] to be successful."¹⁴⁸

In an attempt to resolve Athena's issues, Ethicon made significant updates to the Athena system *in the middle of* M1B work, which caused ChemImage to have to hold an additional lab to help Defendants troubleshoot their hardware issues.¹⁴⁹ During a December 2021 call, Mr. Osmanagic told Dr. Treado that, internally, Defendants had pushed out their decision to charter their Athena hardware, even though Defendants previously communicated that decision had already been reached.¹⁵⁰

¹⁴⁵ See PX-733 at 26 (Nov. 15, 2021 appointment from C. McCombs attaching "Erie Timeline and Gap Analysis with Factors," dated Dec. 16, 2021); P. Ritchie Dep. Tr. at 103:24-104:6 ("Q. ... you also mentioned that there were delays along the way to attempting to achieve Milestone 1B; is that right? A. Correct.").

¹⁴⁶ PX-339 at 7 (June 6, 2021 email attaching "JSC 2021 Meeting 5 – Meeting Minutes", dated May 11, 2021) ("Paul Ritchie discussed proposed language to 'Revised Launch Deadline'" in Section 10.2.2(b) of the Agreement); see also PX-344 at 3 (Aug. 24, 2021 email attaching "JSC 2021 Meeting 6 - Meeting Minutes", dated July 16, 2021) ("Ethicon Proposed Revision to Launch Deadline Status"); PX-208 at 5 (July 14, 2021 JSC Meeting 6 presentation).

¹⁴⁷ PX-391 at 1 (July 19, 2021 chat between E. Osmanagic and P. Ritchie); P. Ritchie Dep. Tr. at 107:7-14; 109:1-11.

¹⁴⁸ PX-391 at 1.

¹⁴⁹ See PX-205 (Feb. 9, 2021 JSC Meeting 2 presentation) (ChemImage holding the "derisk" lab); PX-339 at 5 (June 6, 2021 email attaching JSC 2021 Meeting 5 – Meeting Minutes, dated May 11, 2021); P. Treado Aff. ¶¶ 30-32.

¹⁵⁰ PX-192 at 8 (Dec. 14, 2021 JSC Meeting 11 presentation).

4. **ChemImage Attains the Perfusion Component of M1B**

Despite Ethicon’s delays, in January 2022, ChemImage submitted a report outlining its success in detecting perfusion, or the flow of blood through the circulatory system. Perfusion was one component of M1B. Notably, successfully detecting perfusion marked the first successful pairing of the ChemImage technology with Ethicon’s Athena system.¹⁵¹

As with M1A, the parties followed the process outlined in the Agreement for determining whether the perfusion component of M1B had been satisfied. The JSC agreed to an “acceptance protocol” detailing the criteria for the milestone and ChemImage submitted a Final Perfusion Report to the JSC.¹⁵² On March 9, 2022, after Ethicon reviewed the Final Perfusion Report, the JSC convened and agreed that the perfusion component of M1B had been satisfied.¹⁵³

C. **ChemImage Continues Work Towards M1B Completion**

After achieving the perfusion subset, the parties set their sights on the remaining components of M1B. Under the Agreement, M1B required critical structure detection of five critical structures: Veins, Arteries (sometimes collectively referred to as “Vessels”), Bile Ducts, Ureters, and Neves, including in obscured scenes.¹⁵⁴

As ChemImage worked to complete M1B, the parties jointly agreed to implement two data practices related to ground truth determination: (1) using ignore labels to address uncertainty; and (2) transitioning to “real-time” ground truth determinations.

¹⁵¹ See PX-568 (Jan. 14, 2022 email from M. Steich); *see also* PX-370 (Jan. 14, 2022 Erie Program CS M1B Perfusion Milestone Submission Final Report & Review Meeting presentation).

¹⁵² P. Ritchie Dep. Tr. 93:1-12.

¹⁵³ P. Ritchie Dep. Tr. 93:16-24; *see also* PX-569 at 5 (Jan. 27, 2022 email attaching “Erie Perfusion Milestone 1B” presentation prepared by Cambridge Consultants); PX-570 at 3 (Program Erie Perfusion Feasibility Approval slide deck); PX-356 at 3 (Apr. 26 email attaching “JSC 2022 Meeting 01 - Meeting Minutes”, dated Jan. 25, 2022); PX-410 at 6 (June 13, 2023 email attaching JSC 2022 Meeting 2, dated Mar. 9, 2022).

¹⁵⁴ See Agreement, Ex. B.

1. Defendants Approve Using Ignore Labels To Address Inherent Uncertainty In Live Surgical Scenes

Even with the most skilled surgeon at the helm, collecting data inside of a live animal can result in uncertainty in surgical scenes.¹⁵⁵ This uncertainty is *precisely* why ChemImage’s technology was developed.¹⁵⁶ At the same time, this inherent uncertainty could negatively affect the AI model if, for example, the model was trained on incorrectly labeled data.¹⁵⁷ To address this risk, the parties jointly agreed to use ignore labels on pixels with uncertain ground truth.¹⁵⁸ Ignore labels were used to downweight uncertain pixels in training, and to exclude them all together in testing and evaluation.¹⁵⁹

(a) Cambridge First Proposes Using Ignore Labels For Project Erie

In March 2021, Defendants’ long-time consultant¹⁶⁰, Cambridge, prepared a deck with “labelling strategy” suggestions for ChemImage to utilize in its work on Project Erie and avert issues with uncertainty in surgical scenes.¹⁶¹ Among other suggestions contained in the deck, Cambridge suggested that ChemImage consider adding a “suitable set of labels” to use when the surgeon reviewing the scene could not identify the critical structures with certainty.¹⁶²

Specifically, Cambridge suggested that ChemImage consider using the following labels in its images:

¹⁵⁵ A. Saltman Aff. ¶ 23.

¹⁵⁶ P. Treado Aff. ¶ 7.

¹⁵⁷ D. Sodickson Aff. ¶¶ 56-57, 113.

¹⁵⁸ See Proposed Findings of Fact *infra* § V.C.1(b) (“FOF”).

¹⁵⁹ P. Treado Aff. ¶ 19.

¹⁶⁰ PX-220 (May 30, 2022 “Ground Truth Labelling for Hyperspectral Critical Structure Identification and Cancer localization” presentation prepared by Cambridge Consultants).

¹⁶¹ See PX-462 (Mar. 8, 2021 email attaching “CC Labelling Notes”, prepared by Cambridge Consultants).

¹⁶² PX-462 at 7.

- “Target” (to be used for any image of an “artery, vein, nerve, bile duct, ureter, [or] perfusion”);
- “Obscured Target” (to be used on an image of any of the six targets that were otherwise obscured);
- “Uncertain” (to be used when it was unclear whether the image displayed “Background” or “obscured target”);
- “Background” (for any image that was “certainly NOT any target”);
- “Instruments”; and
- “Ignore” (to be used for “all features that will NOT appear in any realistic use case”).¹⁶³

In this presentation, Cambridge explained that when applying an “Uncertain Target X” label (which would indicate that the image *likely*, but not certainly, contains one of the six targets), it is proper for that annotation to “either be *ignored* or treated as correctly classified if an algorithm classifies them as either background or target X.”¹⁶⁴

Cambridge’s proposed “Uncertain Target X” label was the first iteration of what the parties would later call an “ignore label.” While the name evolved, the labels functioned exactly as prescribed by Cambridge.¹⁶⁵

This suggestion to use “ignore” labels was corroborated with Cambridge’s later research. In May 2022, Cambridge provided Defendants with a presentation containing its “analysis of literature on ground truth labelling of hyperspectral images in the applications of critical structure

¹⁶³ *Id.* at 7.

¹⁶⁴ *Id.* at 5 (emphasis added).

¹⁶⁵ A. Zrimsek Dep. Tr. 83:14-84:1 (Dr. Zrimsek testifying that target specific ignore labels denote uncertain pixels where there is likely a target present).

identification.”¹⁶⁶ The presentation cited multiple examples of studies where pixels with uncertain ground truth were excluded from training and testing in AI models.¹⁶⁷

In connection with a related presentation prepared in June 2022, Cambridge reviewed 31 papers discussing ground truth labeling in hyperspectral and multispectral imaging, including five papers involving using hyperspectral imaging to label critical structures, and concluded in that all but one study dealt with “minimizing uncertainty in labelled pixels ... by only labelling pixels that they were completely certain on.”¹⁶⁸

(b) Defendants Approve The Use of Ignore Labels

In mid-2022, Ethicon and ChemImage established the “Data Review Board” (“DRB”), and held regular meetings with participants from Ethicon, J&J, and ChemImage in order to “resolve open questions about the Erie Program Data Catalog.”¹⁶⁹ The DRB was formed to ensure the “[q]uality of [the] Erie Program data catalog entries & associated ground truth (GT)” and “provide a transparent, consensus driven process to resolve open issues related to the Erie Program data catalog.”¹⁷⁰ Between May 10 and August 25, 2022, the DRB held five meetings.¹⁷¹ Specifically, the DRB issued guidance approving ChemImage’s application of ignore labels.¹⁷² Ethicon’s Project Erie Program coordinator and Defendants’ 30(b)(6) representative, Tamara Lanier,

¹⁶⁶ See PX-220 (May 30, 2022 “Ground Truth Labelling for Hyperspectral Critical Structure Identification and Cancer localization” presentation prepared by Cambridge Consultants).

¹⁶⁷ *Id.* at 6; *see also id.* at 7 (“Annotation was sparse and appears to have been in circles where the surgeon was confident of the correct class.”); *see also id.* at 8.

¹⁶⁸ PX-221 at 27 (June 7, 2022 “CS metrics, CL models, and GT methods” report prepared by Cambridge Consultants); *see also id.* at 28; PX-220 at 6..

¹⁶⁹ P. Treado Aff. ¶¶ 57-58; PX-99 at 6 (May 3, 2022 email attaching DRB Meeting 1 presentation, dated May 10, 2022).

¹⁷⁰ PX-99 at 6.

¹⁷¹ See PX-99; PX-289 (June 16, 2022 DRB Meeting 2); PX-276 (July 19, 2022 DRB Meeting 3); PX-330 (Aug. 15, 2022 DRB Meeting 4); PX-769 at 104-152 (Aug. 25, 2022 DRB Meeting 5).

¹⁷² See PX-769 at 110 (August 25, 2022 DRB Meeting 5).

testified that the DRB approved the use of ignore labels for use “on all of the data” collected for the Project.¹⁷³

The following screenshot from the August 25, 2022 DRB meeting reflects key decisions governing ChemImage’s data practices. Notably, the DRB permitted ChemImage to use ignore labels where the “ground truth cannot be resolved during the [ground truth] review meeting with Ethicon surgical staff,” and noting that these labels “*do not need further review by the DRB*”:¹⁷⁴

Data Review Board (DRB) Meeting 5				
Data Procedures Review Docket				
No.	Question	Date Reviewed	Review Status	DRB Decision
1	Should we use a general ignore label to exclude pixels from our evaluation that have unresolved ground truth?	5/10/2022	Complete	Yes • If ground truth cannot be resolved during the GT review meeting with Ethicon surgical staff, we can use the general ignore label. • Datasets using this approach do not need further review by DRB.
2	Should we use ignore – class labels to exclude 2 nd and 3 rd degree pixels from the 1 st degree evaluation?	5/10/2022	Complete	Yes • Datasets using this approach do not need further review by DRB.
3	Do we have a consensus on the dilation size and usage for different bins? • Bin 1 = 19 and Bin 2 = 9	6/16/2022	Complete	Yes • We have a consensus on the proposed dilation settings at a 50 mm W.O. We will use the same settings for longer W.O. runfile scoring in the meantime but the dilation at longer W.O. may be updated at a later date.
4	How should we categorize mixed degrees of obstructions when reporting results?	6/16/2022	Complete	• Use average to classify degree of obstruction. Provide individual measurements and average in autogenerated slide output.
5	How should we report nerve obstructions?	6/16/2022	Complete	• Use artery obstruction as a surrogate for nerve obstruction classification 2nd vs 3rd. For scenes without artery, the surgeons can provide an estimate on degree of obstruction (2nd or 3rd) for reporting.
6	Can pins be used during ureter demos and milestone evaluation?	6/16/2022	On hold. Pending further evaluation of data by Test/Algo Teams.	

The parties understood that there could be different types of ignore labels. For example, “general” ignore labels refer to an area where ground truth was unclear and could not be established at all, whereas “target-specific” ignore labels refer to regions in which there was reasonable likelihood that target structures were present, but the exact location or path of the structure could

¹⁷³ T. Lanier Dep. Tr. at 182:17-22; *see also id.* at 189:3-5 (“I did not have an understanding that the DRB needed to meet to review the use of an ignore label in every dataset or data file.”).

¹⁷⁴ PX-769 at 110 (Aug. 25, 2022 DRB Meeting 5).

not be determined.¹⁷⁵ In fact, the DRB—on multiple occasions—approved the use of target-specific ignore labels. For example, the “Data File Review” docket outlining the DRB’s decisions at the five DRB meetings makes clear that ChemImage was permitted to use target-specific ignore labels such as “ignore-nerve,” “ignore-ureter,” and “ignore-artery” when the exact location or path of these structures could not be determined.¹⁷⁶

Whether “general” or “target-specific” ignore labels were applied, the effect on ChemImage’s AI model was the same: pixels with general and target-specific ignore labels were *excluded* from evaluation, since performance could not be accurately evaluated without confident ground truth.¹⁷⁷

(c) Defendants Monitor Ignore Label Use And Raise No Concerns

After approving the use of ignore labels through the DRB, Defendants were kept apprised of ChemImage’s *actual* application of ignore labels, as well as the effect that ignore labels could have on ChemImage’s performance metrics.

First, ChemImage made clear at numerous meetings with Ethicon that ChemImage was applying ignore label annotations to the data collected during labs.¹⁷⁸ Defendants also discussed

¹⁷⁵ See PX-214 at 5 (Ignore Label Q&A).

¹⁷⁶ See PX-291 at 9-14 (Aug. 25, 2022 DRB Meeting 5 slide deck).

¹⁷⁷ *Id.*; see also P. Treado Aff. ¶ 72; A. Zrimsek Dep. Tr. at 83:1-84:10.

¹⁷⁸ See, e.g., PX-686 at 24 (June 10, 2022 Erie Program CS M1B EL5 UBN2 Study Test Readiness Review (TRR)); PX-475 at 14 (July 22, 2022 CS M1B EL6 VAB Crawl Study - Test Readiness Review (TRR)); PX-375 at 11 (Aug. 19, 2022 Erie Program CS M1B EL7 VAB Walk Study Test Readiness Review (TRR)); PX-687 at 14 (Oct. 4, 2022 Erie Program CS M1B EL7.5 VAB Jog Study Test Readiness Review (TRR)); PX-26 at 20 (Oct. 21, 2022 CS M1B EL8 VAB Run Study - Test Readiness Review (TRR)).

ignore label use during at least one “Erie Integration” meeting with ChemImage¹⁷⁹ and at JSC meetings.¹⁸⁰

Second, Ethicon’s clinical expert emphatically testified that following the third animal lab, the parties updated the ground truth process specifically because Ethicon felt there were “too many ignore labels” and the parties “wanted to make changes to be able to get the ground truth better.”¹⁸¹

Third, around September 30, 2022, Ethicon specifically tasked Cambridge with analyzing the prevalence and effect of ignore labels on ChemImage’s performance metrics. As part of this exercise, Ethicon, Cambridge, and ChemImage reviewed over 170 runfiles which contained ignore label annotations.¹⁸² Presentations Cambridge prepared for Ethicon after analyzing this subset of the data made clear that ChemImage used ignore labels for training and evaluation, including both general and target-specific ignore labels.¹⁸³ In fact, an October 12, 2022 presentation stated that Cambridge analyzed “how significant the ‘ignore’ categories are in the ground truth dataset.”¹⁸⁴

Despite its awareness of ChemImage’s use of ignore labels, Ethicon **never** prescribed any quantitative limit on the use of ignore labels. Further, prior to sending its termination letter on

¹⁷⁹ See PX-582 at 16 (Jan. 29, 2023 Erie Integration Meeting Weekly Meeting #29).

¹⁸⁰ See, e.g., PX-199 at 25-26 (May 24, 2022 JSC Meeting 5) (stating that where the “DL Model [was] Applied to Test Data Set” in May 16, 2022, the resulting “[c]omputations exclude the pixels labeled with the ignore label”).

¹⁸¹ R. Estape Dep. Tr. at 334:20-336:15; see also PX-251 at 16 (Feb. 8, 2022 “OBS/GT Workstream Obscurements and Ground Truth strategy for 2022 MS1B Labs” presentation) (acknowledging that the “[f]ull extent of targets are often not annotated due to uncertainty in location”).

¹⁸² See e.g., PX-428 (Video Review Ranking Q3 Report spreadsheet), PX-429 (Oct. 20, 2022 email attaching Video Review Ranking Q3 Reviewer Doc spreadsheet); PX-867 (Sept. 30, 2022 Q3 VAB Interim Report: Video Review).

¹⁸³ See PX-607 at Slides 9, 15, 16 (Dec. 28, 2022 email attaching “Review source of Segmentation information” draft report, dated Oct. 28, 2022 prepared by Cambridge Consultants).

¹⁸⁴ PX-623 at 18 (Update: Oct. 12, 2022 Review source of Segmentation information).

March 6, 2023, Ethicon never expressed *any* concern over the quantity of ChemImage's use of ignore labels.

2. The Parties Transition To Real Time Ground Truth Determinations

As Project Erie progressed, the procedures for establishing ground truth also evolved. At all times, Ethicon was apprised of, and expressly approved, the Project Erie study design and data collection practices. Specifically, these items were jointly addressed at JSC Meetings,¹⁸⁵ weekly Project Management meetings,¹⁸⁶ pre-lab Test Readiness Review ("TRR") meetings,¹⁸⁷ and post-lab Lessons Learned meetings ("LL")¹⁸⁸.

¹⁸⁵ See PX-349 (Sept. 21, 2021 email attaching 2021 JSC Meeting 7 Presentation, dated Aug. 24, 2021); PX-784 (Sept. 21, 2021 JSC Meeting 8), PX-193 (Jan. 12, 2021, JSC Meeting 1), PX-192 (Dec. 14, 2021 JSC Meeting 11), PX-205 (Feb. 9, 2021 JSC Meeting 2), PX-206 (Apr. 13, 2021 JSC Meeting 4), PX-208 (July 16, 2021 JSC Meeting 6), PX-195 (Jan. 25, 2022 JSC Meeting 1), PX-198 (Apr. 26, 2022 JSC Meeting 4), PX-199 (May 24, 2022 JSC Meeting 5), PX-200 (June 28, 2022 JSC Meeting 6), PX-201 (Aug. 2, 2022 JSC Meeting 7), PX-202 (Oct. 14, 2022 JSC Meeting 9), PX-203 (Jan. 17, 2023 JSC Meeting 1), PX-224 (Jan. 29, 2020 JSC Meeting 1), PX-190 (Dec. 8, 2020 JSC Meeting 11), PX-217 (Aug. 25, 2022 JSC Meeting 8), PX-237 (May 11, 2021 JSC Meeting 5), PX-226 (Mar. 3, 2020 JSC Meeting 2), PX-227 (Mar. 26, 2020 JSC Meeting 3), PX-236 (Apr. 28, 2020 JSC Meeting 4), PX-238 (June 30, 2020 JSC Meeting 6), PX-239 (Aug. 4, 2020 JSC Meeting 7), PX-240 (Sept. 8, 2020 JSC Meeting 8), PX-225 (Feb. 28, 2023 JSC Meeting 2), PX-229 (Mar. 9, 2021 JSC Meeting 3), PX-188 (Dec. 1, 2021 JSC Meeting 10), PX-318 (Jan. 25, 2022 JSC Meeting 2), PX-82 (Apr. 25, 2022 email attaching JSC 2022 Meeting 4, dated April 26, 2022), PX-354 (May 23, 2022 email attaching JSC 2022 Meeting 5, dated May 24, 2022), PX-80 (June 28, 2022 email attaching JSC 2022 Meeting 6, dated June 28, 2022), PX-114 (May 22, 2022 email attaching JSC 2022 Meeting 5, dated May 24, 2022), PX-76 (Dec. 14, 2021 email attaching JSC 2021 Meeting 11, dated Dec. 14, 2021), PX-110 (Feb. 23, 2023 email attaching JSC 2023 Meeting 2 Minutes, dated Feb. 28, 2023), PX-39 (Jan. 13, 2023 email attaching JSC 2023 Meeting 1, dated Jan. 17, 2023), PX-79 (Oct. 13, 2023 email attaching JSC 2022 Meeting 9, dated October 14, 2022), PX-346 (Oct. 5, 2020 email attaching JSC Meeting 9, dated Oct. 6, 2020), and PX-342 (Jan. 13, 2023 email attaching JSC 2023 Meeting 1, dated Jan. 17, 2023).

¹⁸⁶ See PX-508 at 2 (Apr. 9, 2020 Weekly Erie PM Meeting); PX-694 at 2 (July 14, 2022 Weekly PM Meeting); PX-712 at 2 (Apr. 7, 2022 Weekly PM Meeting).

¹⁸⁷ See P. Treado Aff. ¶ 45; PX-686 (June 10, 2022 Erie Program CS M1B EL5 UBN2 Study Test Readiness Review (TRR)); PX-475 (July 22, 2022 CS M1B EL6 VAB Crawl Study - Test Readiness Review (TRR)); PX-375 (Aug. 19, 2022 Erie Program CS M1B EL7 VAB Walk Study Test Readiness Review (TRR)); PX-687 (Oct. 4, 2022 Erie Program CS M1B EL7.5 VAB Jog Study Test Readiness Review (TRR)); PX-26 (Oct. 21, 2022 CS M1B EL8 VAB Run Study - Test Readiness Review (TRR)); PX-822 (Nov. 7, 2022 Erie Program CS M1B EL9 VAB VOC Study Test Readiness Review (TRR)).

¹⁸⁸ PX-668 (June 17, 2022 Erie Program CS M1B EL4 UBN CAFO Study Lessons Learned (LL) Meeting); PX-585 (July 11, 2022 Erie Program CS M1B EL5 UBN 2 Study Lessons Learned (LL) Meeting); PX-

(a) Post-Lab Ground Truth Process In ELs 1-3

During Erie Labs (“ELs”) 1-3, the process for establishing ground truth included having a surgeon conduct surgery on a porcine model and provide feedback on the structures they were able to identify to ChemImage’s Ground Truth Team (the “GT Team”).¹⁸⁹ The surgeons performing these labs were primarily Ethicon surgeons.¹⁹⁰ After an EL concluded, the GT Team would annotate each pixel of every image from the surgical scenes collected at the labs based on feedback from the surgeons.¹⁹¹ For any images where portions of the scene were still unclear, the parties would hold “GT Review Meetings” *one to two weeks after* the lab to see if the surgeons could review the images again and establish ground truth.¹⁹²

This process was time-consuming and often ineffective. ChemImage’s GT Team would be required to follow-up with surgeons weeks after the labs had concluded, and at that point, fading memories made it more difficult to establish ground truth with certainty.¹⁹³ In an internal Ethicon presentation from May 2022, Ethicon recognized these issues and noted that there had been “[s]ignificant challenges with dataset collections for deep learning and ground truth annotation purposes.”¹⁹⁴

819 (Aug. 19, 2022 Erie Program CS M1B EL6 VAB Crawl Study LL Meeting); PX-511 (Sept. 20, 2022 CS M1B EL7 VAB Walk Study - LL Meeting).

¹⁸⁹ P. Treado Aff. ¶ 54.

¹⁹⁰ A. Zrimsek Dep. Tr. 25:17:18 (“ChemImage was in the suite as well, but the surgeons were primarily from Ethicon as far as I understand.”).

¹⁹¹ P. Treado Aff. ¶ 52.

¹⁹² *Id.*

¹⁹³ A. Saltman Aff. ¶¶ 31, 35-36; P. Treado Aff. ¶¶ 52-53.

¹⁹⁴ PX-583 at 4 (May 22, 2022 Erie Strategy Discussion slide deck).

Notably, when the DRB reached its May 10, 2022 decision allowing for general ignore labels “if ground truth cannot be resolve *during the GT review meeting* with Ethicon surgical staff,” the parties were still conducting a post-lab GT review meeting, weeks after the lab.¹⁹⁵

3. Realtime Ground Truth Process In ELs 4-8

In May 2022, at the request of ChemImage’s CMO, Dr. Saltman (who also began participating in the labs as a surgeon),¹⁹⁶ the parties implemented an updated ground truth review process. Under the updated process, the parties would record the ChemImage and Ethicon surgeons’ narrations while they were operating so their impressions about what was present in each surgical scene were captured in real time.¹⁹⁷ Critically, ChemImage’s GT Team was also present at labs and would annotate a representative image from each surgical scene *during the lab*,¹⁹⁸ allowing ChemImage to discuss and clarify any uncertainty regarding ground truth with the surgeons *in real-time*.¹⁹⁹ The Ethicon and ChemImage surgeons and the ChemImage annotators would then reach *consensus* on ground truth *while in the lab*.²⁰⁰

Because each run file is comprised of hundreds of nearly identical scenes and an exponential amount of pixels, further annotation of the remaining scenes in the run file would

¹⁹⁵ PX-291 at 8 (Aug. 25, 2022 Data Review Board Meeting 5) (“If ground truth cannot be resolved *during the GT review meeting with Ethicon surgical staff*, we can use the general ignore label. Datasets using this approach do not need further review by DRB.”).

¹⁹⁶ A. Saltman Aff. ¶ 32.

¹⁹⁷ P. Treado Aff. ¶¶ 54-55; PX-585 at 24 (July 11, 2022 Erie Program CS M1B EL5 UBN 2 Study Lessons Learned (LL) Meeting); *see also* A. Zrimsek Dep. Tr. at 25:2-19 (“Q. And the surgeons would narrate or describe the scene in real-time in the surgical suite, right? A. Yes. And the surgeons who attended these labs were from ChemImage, correct? A. No. Q. ... What surgeons attended? A. I believe the surgeons were from Ethicon. ... ChemImage was in the suite as well, but the surgeons were primarily from Ethicon as far as I understand.”).

¹⁹⁸ A. Saltman Aff. ¶¶ 35-36.

¹⁹⁹ P. Treado Aff. ¶¶ 54-55; *see also* R. Estape Dep. Tr. 328:3-4. (“The only way to get accurate ground truth is to do it contemporaneously.”).

²⁰⁰ A. Saltman Aff. ¶ 35.

occur after the lab.²⁰¹ However, if an annotator on ChemImage’s GT Team had any questions when applying these post-lab annotations, they would refer back to the recorded surgical narration—*which already captured the Ethicon and ChemImage surgeon’s consensus on ground truth*—to resolve it.²⁰² With the live annotation and video capture of the surgeons’ narration of the surgical scenes during the lab, post-lab ground truth meetings (*i.e.*, to discuss ground truth with the surgeons weeks later) were no longer necessary or useful.²⁰³

This new ground truth workflow was discussed with and approved by Ethicon.²⁰⁴ The new workflow promoted efficiency and Defendants never requested that the post-lab GT Review meetings be reinstated.²⁰⁵

4. Ethicon Delays Continue to Hamper M1B Progress

Issues with Defendants’ Athena hardware required for completion of M1B continued throughout 2022. In June 2022, two of the “Top 5 Technical Risks” that Defendants identified for Project Erie concerned Athena. Specifically, Defendants identified the “Athena system integration” as a “High-level risk” and “Multispectral autoexposure” on Athena as a “Medium-

²⁰¹ P. Treado Aff. ¶ 54.

²⁰² A. Saltman Aff. ¶¶ 30, 35, .

²⁰³ A. Saltman Aff. ¶ 36; P. Treado Aff. ¶ 55. Although the parties continued to hold Ground Truth review meetings after EL4 and EL5, once the improved ground truth workflow was in place, the post-lab meetings were deemed unnecessary by the parties, and the practice was discontinued. *See* A. Zrimsek Dep. Tr. at 27:5-28:15 (“We worked on improving the ground truth procedures with the video recordings, so then we no longer found those meetings necessary ... we were able to answer all of the questions that we needed during the lab and using the video recording *[W]e found that the surgeons had a better memory if you asked them while they were doing the surgery. Two weeks later they tend to forget.*”) (emphasis added).

²⁰⁴ *See* PX-585 at 24 (July 11, 2022 Erie Program CS M1B EL5 UBN 2 Study Lessons Learned (LL) Meeting); PX-354 at 11 (May 23, 2022 email attaching JSC 2022 Meeting 5, dated May 24, 2022); *see also* PX-200 at 25 (June 28, 2022 JSC Meeting 6) (listing “improved ground truth & obscuration strategy based on competitive intelligence, technology literature search & clinical utility” as one of the “Risk Mitigation” strategies on the “Erie Program Joint Leadership Dashboard”).

²⁰⁵ *See, e.g.*, PX-597 at 18 (June 15, 2022 Erie Integration Meeting Weekly Meeting #13).

level risk.”²⁰⁶ Further, in a June 24, 2022 “Erie Program Technical Review” presentation to J&J’s Peter Shen, Defendants noted that three of the “Erie Top 5 Technical Risks” for Project Erie concerned development challenges with J&J’s own Athena platform.²⁰⁷

VI. CHEMIMAGE ACHIEVES THE VAB ACCEPTANCE CRITERIA

A. Defendants Ask ChemImage To Submit A Final Report On VAB

In mid-2022, the then-Global Head of R&D Innovation for J&J’s MedTech Division,²⁰⁸ Peter Shen, conducted a technical “deep dive” into Project Erie.²⁰⁹ Following this “deep dive,” Mr. Shen provided a “revised recommendation” that ChemImage “[p]rioritize feasibility efforts targeting Veins, Arteries and Bile Ducts (VAB) by year end 2022 with final analysis and report out completed by February 2023” and to “[p]ostpone Ureter and Nerve feasibility efforts until 2023.”²¹⁰ The parties referred to this partial M1B workflow as “VAB.”

The JSC then agreed on the acceptance criteria that ChemImage would have to meet for the VAB portion of M1B (the “VAB Acceptance Criteria”) as follows:²¹¹

²⁰⁶ PX-307 at 34 (June 24, 2022 Erie Program Technical Review Presentation); *see also* PX-321 at 31 (June 17, 2022 Project Erie Amendment of Development Agreement with ChemImage Corp. Presentation stating that “[t]o improve the probability of [Project Erie’s] success, new hardware and software levers were introduced,” among other changes).

²⁰⁷ *See* PX-502 at 34 (June 24, 2022 Erie Program Technical Review Presentation); *see also* PX-307 at 20 (June 24, 2022 Erie Program Technical Review Presentation stating that Defendants were still “awaiting [an] upgrade” to the Athena hardware sensor that would enable “faster read-out” of results and “Realtime deep learning detection in-vivo.”).

²⁰⁸ P. Shen Dep. Tr. at 7:8-8:16.

²⁰⁹ PX-306 (June 27, 2022 email attaching Project Erie Deep Dive Assessment); PX-280 at 1-2 (July 7, 2022 email from P. Shen).

²¹⁰ PX-280 at 2 (July 7, 2022 email from R. Gooding); *see also* P. Treado Aff. ¶ 44; *see also* P. Shen Dep. Tr. at 138:1-139:4, 139:8-11, 140:1-17; PX-784 at 11 (Sept. 21, 2021 JSC Meeting 8 Presentation) (explaining that by September 2021, Ethicon was considering splitting M1B into veins, arteries, and perfusion (PVA) and pushing out work on bile ducts, ureters, and nerves (UBN)).

²¹¹ *See* PX-2 (the “VAB Final Report”) at 17; *see also* PX-313 at 10 (Nov. 29, 2022 JSC Meeting 10 Presentation). *Sensitivity* refers to how well the model can identify true positives in a test set; in other words, the probability of a positive detection where there is a structure. *Specificity* relates to how well the

Erie Program CS MIB VAB Acceptance Protocol Reflecting VAB Performance Requirements (2-Dec-2022)	
Technology	<ul style="list-style-type: none"> Demonstrate: <ul style="list-style-type: none"> Single-Target Tasks: Veins, Arteries, Bile Duct - Mean of Sensitivity, Mean of Specificity, Mean of AUC, a 95% AND Mean PPV, Mean NPV a Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity Multi-Target: Mean of Sensitivity, Mean of Specificity, Mean of AUC a 95% AND Mean PPV, Mean NPV a Thresholds Determined by Prevalence @ 80% Sensitivity & Specificity Obscuration: 0-5 mm natural Working Distance: VA: 50 mm; B: 80 mm Angle: 0° (Normal Incidence) Characterize: <ul style="list-style-type: none"> Multi-Target: Arteries + Veins, Bile Duct + Artery Obscuration: 0-5 mm natural Obscuration: > 5-10 mm natural obstructions Working Distance: VA: 80 mm Angle: ± 30° Video Review: of Representative Videos (Clinical Evaluation Scale 2 to 3 score, Cholecystitis, Ethicon, 3rd party - OC) Scope Movement: VAB detection with handheld trocar (port constrained) & robotic movement Negative Control Scenes: Show additional 10% (of total demonstrated N) to detection scenes (e.g., Bile Duct in Back scene) Notes: <ul style="list-style-type: none"> Detection Threshold: Results to be presented stratified per critical structure, multi-target combination, procedure, obscuration level, target diameter > 1mm and SLG vs. SLG/6/7. Characterize ability and tradeoffs for higher sensitivity or specificity
Statistics	<ul style="list-style-type: none"> Data to be presented in a statistical manner across full data set (Disseminated & Consistent Case Configuration Settings) and consulted with Ethicon Biostatistician Statistical analysis to be run on all collected data sets except where data must be excluded (Data Exclusion and Inclusion to be signed on jointly)
Technology	<ul style="list-style-type: none"> Final based analysis Post-processed statistical summary Seeing and all reported metrics must be based on the real-time embedded pipeline with no additional processing of the embedded results outside of sensitivity setting optimization evaluation Near real-time (min 2fps) demonstration in Run Lab & Surgeon VDC with detection and overlay. Characterize ability and tradeoffs to achieve real-time (≥30 fps) Must allow user to operate under RGB light (or white light) while also detecting the critical structures using the Erie technology VAB detection results must be mutually independent and not overlap with perfusion Detection-related algorithms must be specific to features of structures not individual scenes (e.g., Artery detection, Vein detection, Bile Duct Detection) No target labeling-based calibration allowed, should be built into algorithms Allowed to auto-expose calibration between targets/locations/scenes Allowed to adjust Sensitivity Control prior to Near Real-Time demonstrations Max 10 Ws but ≤ 5 s an Objective (Five to Nine) Requirement. Characterize ability and tradeoffs to minimize waittimes as a function of performance Deep learning algorithm review and analysis (exclusion criteria, ignore label criteria, temporal performance, saliency map or intelligence AI prior to 15 Jan 2023)
Preclinical Model	<ul style="list-style-type: none"> Animal Model: Porcine model LAR and Chole relevant scenes as best demonstrated in animal model Critical Structure Targets: Veins, Arteries, Bile Duct Procedural Workflow: Cholecystectomy and Lesser Arterial Resection (LAR) Multi-Target: Arteries + Veins, Bile Duct + Artery Obscuration: Natural obstructions found and measured via ultrasound in porcine model (no CAPCO) Scope Working Distance: Demonstrate 50 mm for VA, 80 mm for B. Characterize 80 mm for VA Scope Working Angles: Demonstrate 0°, Characterize ± 30° Scope Movement: Characterize handheld trocar and robotic scope movement
Internal Feedback & External VOC	<ul style="list-style-type: none"> Internal Feedback and External VOC Goals: <ul style="list-style-type: none"> Receive feedback on ability to detect and differentiate between Veins, Arteries and Bile duct Receive feedback on ability to aid in LAR procedural workflow by helping surgeons identify arteries specifically the RMA and SMA/Jerms junction, and the BMV specifically Receive feedback on ability to aid in Chole procedural workflow by helping surgeons identify the artery specifically the cystic artery, and bile duct including the biliary tree: cystic, hepatic, common bile duct. Both LAR and Chole clinical scenes are to be demonstrated/characterized in full obscuration Receive feedback on technical assessment of Erie Technology Internal Feedback Participants: 2 CI Surgeons, Ethicon JSC Members + invited Ethicon leadership observe detections and provide feedback in SLG at VIP Leadership demo External VOC Participants: Up to 6 external: Colorectal (4) and General surgeons (2) who actively perform colorectal resections and cholecystectomies either laparoscopically or robotically
Reviews	<ul style="list-style-type: none"> VOC Feedback JSC Review Internal Ethicon Working and Leadership Review External 3rd Party Review

Notably, the VAB Acceptance Criteria does **not** prescribe any required sample size (also referred to as an “N” value), let alone any required sample size at particular obscuration depths.²¹² And aside from requiring negative control scenes at “10% (of total demonstrated N),” the VAB Acceptance Criteria does not set any parameters for selection of negative control scenes.²¹³ Defendants’ machine learning expert, Dr. Hannaford, confirmed this.²¹⁴

model can identify true negatives; in other words, the probability of a negative detection where there is not a structure. See D. Sodickson Aff. ¶¶ 73, 74.

²¹² See VAB Final Report at 17; see also PX-769 at 110 (Aug. 25, 2022 Data Review Board Meeting 5 Presentation, instructing to “[u]se average to classify degree of obscuration” when reporting results, rather than any required sample size at particular obscuration depths) (emphasis added).

²¹³ *Id.*

²¹⁴ See B. Hannaford Dep. Tr. at 80:2-5 (Q: “In these acceptance criteria, there is nothing that describes how ChemImage should train its model, right? A: Yes, I think that’s right.”); *Id.* 85:3-10 (Q: “The acceptance criteria does not prescribe any necessary sample size, correct? A: Not with a number, correct. Q: And the acceptance criteria does not prescribe any necessary sample size at each specific obscuration depth, correct? A: Not by a number...”); *Id.* at 90:18-22 (“Q: And the acceptance criteria does not prohibit use of scenes other than LAR or cholecystectomy, correct? A: I don’t recall seeing that either.”).

B. The Interim and Draft VAB Report

On September 30, 2022, ChemImage submitted an interim report outlining its success on the VAB subset of M1B (the “Interim VAB Report”).²¹⁵ Although both Ethicon and Cambridge reviewed and provided feedback on the Interim VAB Report,²¹⁶ neither commented on or inquired about the prevalence of ignore labels.²¹⁷ They also did not comment on or inquire about the use of negative control scenes or any other purportedly missing sections of the report. ChemImage also submitted a near-final VAB Final Report to Defendants on December 13, 2022.²¹⁸ Defendants did not raise any concerns to ChemImage in response to the near-final report.

C. The VAB Final Report

On December 16, 2022, ChemImage submitted the VAB Final Report and provided Defendants with all requested data.²¹⁹ The VAB Final Report included an executive summary demonstrating successful achievement of the VAB Acceptance Criteria, including detection performance results, statistical considerations, specific examples of data, and a gap assessment.²²⁰

After the VAB Final Report was submitted, ChemImage asked Defendants multiple times to convene a JSC meeting so that the VAB Final Report could be assessed and voted on—as required by the Agreement and as was done with M1A and Perfusion.²²¹ Defendants refused.²²²

²¹⁵ See PX-780 (“Interim VAB Report”).

²¹⁶ P. Treado Aff. ¶ 61.

²¹⁷ *Id.*

²¹⁸ See Interim VAB Report; PX-437 (Dec. 13, 2022 email from Michael Steich (“We are happy to release a DRAFT pre-read of the VAB Final Report”).

²¹⁹ See VAB Final Report; P. Treado Aff. ¶ 67.

²²⁰ See *generally* VAB Final Report.

²²¹ P. Treado Aff. ¶¶ 68-69.

²²² See P. Treado Aff. ¶¶ 68-69; PX-811 (Mar. 7, 2023 email from F. Fernandez declining M. Steich’s request for “JSC Touchpoint Follow-Up Session”); PX-587 (March 7, 2023 Email from C. Denys, President of ChemImage, to F. Fernandez and T. Lanier acknowledging that they “declined the meeting”).

Instead, over an approximately one month period, ChemImage received and responded to several rounds of Q&A put forward by Ethicon regarding basic tenets of ChemImage’s technology and ChemImage’s use of ignore labels in the VAB Final Report.²²³ This Q&A consisted of four rounds of questions, many of which underscored Defendants’ lack of basic understanding of ChemImage’s technology and the joint decisions the parties had already reached on ignore labels.²²⁴

For example, in response to certain questions, ChemImage explained to Defendants that an “Ignore label” generally refers to an annotation that ChemImage scientists added to pixels in an image where the ground truth for part of an image could not be resolved so that images with some ground truth uncertainty could still be used in training and not discarded wholesale.²²⁵ These were questions the parties had previously discussed at length and reached agreement on at the DRB meetings, which Ethicon attended.²²⁶

The first three rounds of questions by Ethicon involved general questions on understanding ChemImage’s use of ignore labels, including how ignore labels were counted in calculations.²²⁷ ChemImage explained that the process of applying ignore labels was in line with the DRB decisions.²²⁸ In the fourth and final round of questions, sent to ChemImage on February 9, 2023, Ethicon asked for the first time about specific examples of run files²²⁹ where ignore labels were

²²³ See PX-214 (Feb. 14, 2023 Ignore Labels Q&A Presentation); see also P. Treado Aff. ¶ 70..

²²⁴ See *id.*

²²⁵ See Proposed Findings of Fact *supra* § V(C)(1).

²²⁶ See PX-289 (June 16, 2022 DRB Meeting 2 Presentation).

²²⁷ See generally PX-214 (Feb. 14, 2023 Ignore Labels Q&A Presentation).

²²⁸ See *id.* at 67.

²²⁹ In the VAB Final Report, a “runfile” referred to video recorded during an EL focused on the identification of a specific critical structure. See P. Treado Aff. ¶ 15.

present.²³⁰ ChemImage provided answers to each of the inquiries over 21 slides. After the fourth round of Q&A, Ethicon did not ask any additional questions.

Most importantly, Ethicon *never* told ChemImage that it had not met the quantitative performance metrics in the VAB Acceptance Criteria. Instead, Ethicon deemed the VAB Final Report “unevaluable” after purporting to “randomly” sample a subset of 50 of 1,239 runfiles used in the VAB Final Report.²³¹ Dr. Hansen described this process as, “not . . . any systematic method or anything, we just randomly picked some things.”²³² Ethicon’s machine learning expert admitted that he did not analyze whether this purported sample was representative of the runfiles in the VAB Final Report.²³³

After receiving Defendants’ Ignore Label Q/A, ChemImage proactively set out to demonstrate to Ethicon that under any conceivable treatment of ignore labels, it achieved the performance metrics in the VAB Acceptance Criteria.²³⁴ ChemImage ran various “linkage scenarios,” which quantitatively proved that under every conceivable treatment of ignore labels, ChemImage *still* met the required performance metrics of the VAB Acceptance Criteria.²³⁵

²³⁰ See PX-214 at 4 (Feb. 14, 2023 Ignore Labels Q&A Presentation); *see also* PX-109 (Mar. 9, 2022 email from M. Conner).

²³¹ PX-2 (VAB Final Report) at 62; S. Hansen Dep. Tr. at 5:3-36:19, 37:16-38:8, 45:5-10, 138:24-139:24.

²³² S. Hansen Dep. Tr. at 44:5-13.

²³³ B. Hannaford Dep. Tr. 75:14-18 (Q. You didn’t analyze whether the subset of data that Ethicon used was a representative sample from that final report, correct? A. I would stay that’s correct.).

²³⁴ ChemImage referred to this process as re-running its metrics under different “linkage” scenarios. *See* PX-730 at 9. (Feb. 27, 2023 email from M. Steich to T. Lanier and F. Fernandez attaching JSC 2023 Meeting 2, dated Feb. 28, 2023); *see also* B. Hannaford Dep. Tr. at 75:23-76:2 (“Q. To your knowledge, Ethicon never attempted to validate the entire set of data submitted for the final report, correct? A. Correct.”).

²³⁵ P. Treado Aff. ¶ 73; PX-730 at 9.

ChemImage sent these results to Ethicon,²³⁶ but Ethicon refused to engage. Ethicon even *cancelled* the upcoming JSC meeting where these “linkage scenarios” were slated to be discussed.²³⁷

VII. ETHICON’S PURPORTED “FOR CAUSE” TERMINATION

A. Defendants Recognized They Could Not Terminate “For Cause” For Failure To Meet A Subset Of A Milestone

Although M1B required detection of five critical structures (i.e., VAB *plus* Ureters and Nerves),²³⁸ *Defendants* asked ChemImage to submit a Final Report on VAB only.²³⁹ At no point did the JSC decide that Ethicon’s unilateral assessment of the VAB Final Report could lead to program termination.²⁴⁰ Likewise, as Paul Ritchie, Ethicon’s JSC representative and Project Erie lead, conceded, the Agreement did not provide any termination bases for failure to meet a *subset* of a milestone.²⁴¹

Ethicon’s internal documents confirm that Defendants understood that they could not terminate the agreement for failure to meet a *subset* of a milestone. In 2022, Ethicon considered renegotiating the Agreement to give it added flexibility “to terminate if X number of target groups not achieved” or to terminate if just a subset of M1B (e.g., “PVA”), was not achieved by a certain date.²⁴² By April 2022, Ethicon solidified its plan to revise the Agreement to include

²³⁶ PX-730 at 9 (Feb. 27, 2023 email from M. Steich to T. Lanier and F. Fernandez attaching JSC 2023 Meeting 2, dated Feb. 28, 2023).

²³⁷ PX-730 at 9; PX-41 (Feb. 27, 2023 email from T. Lanier to ChemImage personnel asking to cancel the upcoming JSC meeting).

²³⁸ See Agreement, Ex. B-1 at 8.

²³⁹ PX-313 at 10 (Nov. 29, 2022 JSC Meeting 10 Presentation); VAB Final Report at 18.

²⁴⁰ P. Treado Aff. ¶¶ 68-69.

²⁴¹ See Agreement §10.3.2; see also P. Ritchie Dep. Tr. at 103:9-13 (“Q. And to your knowledge, does the Agreement say Ethicon can terminate upon rejection of a partial report? A. Not to my knowledge.”).

²⁴² PX-577 (Proposed Revisions to the Research, Development, License and Commercialization Agreement).

“checkpoints” at subsets of a Milestone to give Ethicon the “option to partially terminate efforts on individual targets if minimum milestone criteria are not achieved by target date,” including the right to “terminate the [A]greement completely right away” if ChemImage failed to meet these “checkpoints.”²⁴³

On June 17, 2022, Ethicon presented the case for amending the Agreement to Susan Morano, J&J’s then-Vice President of Business Development and Strategic Operations, and Kurt van den Bosch, J&J’s CFO for MedTech.²⁴⁴ Ethicon reiterated to J&J that a benefit to renegotiating the Agreement would be the addition of “checkpoints” at which point in time Ethicon could terminate the Agreement for failure to meet a subset of a Milestone.²⁴⁵

However, J&J’s senior leadership *rejected* Ethicon’s proposal and declined to renegotiate the Agreement.²⁴⁶ The Parties *never* amended the Agreement to allow Ethicon to terminate the agreement for failure to achieve VAB as a *subset* of M1B.²⁴⁷

B. The Termination Letter

On March 6, 2023, Ethicon provided ChemImage with a letter (the “Termination Letter”) purporting to “terminate the Agreement for cause for failure to achieve a Development Milestone.”²⁴⁸ The Termination Letter states that, “[i]n particular, a final report provided on

²⁴³ PX-810 at 7 (Apr. 23, 2022 Email from F. Fernandez) (emphasis in original).

²⁴⁴ See PX-321 (June 17, 2022 Presentation on Amendment of Development Agreement).

²⁴⁵ See *id.* at 23 (“Right to terminate Agreement” contingent on “Minimum Criteria ... NOT met”).

²⁴⁶ See PX-280 at 2 (July 7, 2022 email from R. Gooding, writing “we are providing a revised recommendation to not pursue approvals for renegotiation of the agreement at this time...”)

²⁴⁷ *Id.*

²⁴⁸ See PX-3 (“Termination Letter”) at 2.

December 16, 2022, for a *subset* of the critical structures, veins, arteries, and bile ducts (collectively, “VAB”) *that are a part of Milestone 1B* in the Agreement, is not evaluable.”²⁴⁹

Specifically, Ethicon identified three purported criticisms of the VAB Final Report: “uncertainty with respect to negative controls, use of omnipresent ignore labels, and data discrepancies between a preliminary report and the final report[.]”²⁵⁰ The Termination Letter also pointed to “additional challenges faced with ureters and nerves,”²⁵¹ but ignored the JSC’s agreement to postpone work on ureters and nerves until 2023.²⁵² Notably, the Termination Letter does not state that ChemImage failed to meet the performance metrics of the VAB Acceptance Criteria agreed to by the JSC.

While Ethicon’s Termination Letter claimed there were “other” “errors and flaws in collecting and processing data,” it did not—and still has not—explained those reasons.²⁵³ Indeed, Ms. Lanier testified that Ethicon did not “provide any other written information to ChemImage regarding the basis for termination other than” what was contained in the Termination Letter.²⁵⁴ And when asked if there were “bases other than those stated in the March 6, 2023 Termination Letter” on which Ethicon relied in terminating the Agreement, Ms. Lanier—the corporate designee for both Ethicon and J&J—responded by “refer[ring] ChemImage to the Agreement which speaks for itself.”²⁵⁵

²⁴⁹ *Id.* (emphasis added)

²⁵⁰ *Id.*

²⁵¹ *Id.* at 3.

²⁵² See PX-280 at 2 (July 7, 2022 email from R. Gooding); see also P. Treado Aff. ¶ 44; PX-784 at 11 (by September 2021, Ethicon was considering splitting M1B into veins, arteries, and perfusion (PVA) and pushing out work on bile ducts, ureters, and nerves (UBN)).

²⁵³ See generally, Termination Letter.

²⁵⁴ T. Lanier Dep. Tr. at 213:21-214:2.

²⁵⁵ PX-588 (Ethicon’s Responses and Objections to ChemImage’s Second Set of Interrogatories) at 26-27.

The Termination Letter also asserted, in conclusory fashion, that “previously completed labs, data collection, and annotation processes would need to be *reworked and repeated*.”²⁵⁶ Notably, however, Defendants cancelled all previously scheduled labs.²⁵⁷ Because the labs were conducted at J&J-owned and operated facilities,²⁵⁸ Defendants’ cancellation of these labs made it impossible for ChemImage to perform any additional work on Project Erie, including any activities that might cure Defendants’ fabricated termination bases, including, for example, “reworking or repeating” data collection. Notably, Mr. Ritchie, a former Ethicon JSC member who approved ChemImage’s achievement of M1A and Perfusion, agreed that, under the Agreement, ChemImage would be entitled to do a “rework” to resolve any issues Ethicon raised in response to submission of a final Milestone report.²⁵⁹

C. ChemImage Attempts To Understand The Purported Termination Bases In Order To Cure

On March 17, 2023, ChemImage wrote to Ethicon to request in-person meeting of senior executives, consistent with Section 12.2 of the Agreement.²⁶⁰ ChemImage also explained that the Termination Letter:

²⁵⁶ See Termination Letter at 2 (emphasis added).

²⁵⁷ See PX-615 at 2 (Feb. 6, 2023 email from Tamara Lanier to ChemImage cancelling the next week’s Ureter Nerve lab); PX-41 (Feb. 27, 2023 email from Tamara Lanier to ChemImage personnel asking to cancel the upcoming JSC meeting); PX-587 (Mar. 7, 2023 email from C. Denys stating that Ethicon’s T. Lanier and F. Fernandez declined the JSC meeting scheduled for that same day); PX-811 (Mar. 7, 2023 email from F. Fernandez declining the Mar. 7, 2023 JSC meeting).

²⁵⁸ See, e.g., PX-686 (June 10, 2022 CS M1B EL5 UBN2 Study Test Readiness Review); PX-475 (July 22, 2022 M1B EL6 VAB Test Readiness Review); PX-375 (Aug. 19, 2022 CS M1B EL7 VAB Walk Study Test Readiness Review); PX-687 (Oct. 4, 2022 CS M1B EL7.5 VAB Jog Study Test Readiness Review); PX-26 (Oct. 21, 2022 CS M1B EL8 VAB Run Study Test Readiness Review); PX-28 (Nov. 17, 2022 CS M1B EL9 VAB VOC Test Readiness Review); PX-822 (Nov. 18, 2022 CS M1B EL9 VAB VOC Study Test Readiness Review); see also T. Lanier Dep. Tr. at 147:5-8 (“[T]he majority of the labs were done for Milestone 1B in Ethicon’s facilities”).

²⁵⁹ P. Ritchie Dep. Tr. 67:9-14.

²⁶⁰ PX-172 at 152-155 (Mar. 17, 2023 letter from J. Cohen).

[D]oes not specify in sufficient detail the nature of the alleged breach, failing to comply with the notice requirements of Section 10.3.1 and leaving ChemImage unable to cure the purported deficiencies. The assertion that the Final Report reflects “errors and flaws in collecting and processing data” is unsubstantiated and contradicted by the facts. ChemImage used ignore labels and other processes developed in collaboration with and approved by Ethicon in both Test Readiness Reviews and Data Review Board Meetings. ChemImage, Ethicon, and Ethicon’s third-party consultant, Cambridge Consultants, all participated in the Data Review Board meetings, and all understood and approved the processes that ChemImage ultimately used to demonstrate technological feasibility for M1B To the extent Ethicon believes that something else was required, it must detail it in a manner that would allow ChemImage to understand and cure the alleged deficiencies²⁶¹

On March 29, Ethicon acknowledged ChemImage’s meeting request but did not provide any additional information regarding the bases alleged in the Termination Letter.²⁶² Ms. Lanier confirmed that Defendants never prepared any other written communication, slide deck or any other document outlining its bases for termination.²⁶³

On April 7, 2023, representatives from Ethicon and ChemImage met in Atlanta to discuss ChemImage’s purported breach. Dr. Treado, Dr. Cohen, and Rich Ruben (a ChemImage Board member) attended for ChemImage.²⁶⁴ Tamara Lanier and Francesc Fernandez attended in-person for Defendants, and Steen Hansen, one of the technical leads for Project Erie, appeared remotely over a video call.²⁶⁵ In total, the meeting lasted for just under an hour, as ChemImage was told that the Ethicon employees had to catch their return flights.²⁶⁶

²⁶¹ *Id.* at 153.

²⁶² PX-588 at 26-27 (Ethicon’s Responses and Objections to ChemImage’s Second Set of Interrogatories).

²⁶³ *See* T. Lanier Dep. Tr. at 276:8-15.

²⁶⁴ PX-777 at 2 (Apr. 10, 2023 email from P. Treado) ; J. Cohen Aff. ¶ 52; P. Treado Aff. ¶ 76.

²⁶⁵ T. Lanier Dep. Tr. at 211:19-212:3.

²⁶⁶ PX-777 at 2, 4 (Apr. 10, 2023 email from P. Treado); PX-873 at 1-2; (Apr. 6, 2023 email chain with J. Cohen, F. Fernandez, *et al.*); J. Cohen Aff. ¶ 53.

During the meeting, ChemImage repeatedly asked Ethicon to provide substantive and quantitative details on the purported termination bases and how they might be cured.²⁶⁷ Defendants generally reiterated the same surface level complaints about ChemImage’s work on VAB—none of which was sufficiently detailed to allow ChemImage to cure. However, in an abrupt departure from the Termination Letter, which stated that “previously completed labs, data collection, and annotation processes would need to be *reworked and repeated*,”²⁶⁸ Mr. Fernandez and Ms. Lanier repeatedly told ChemImage that the purported breaches were *not* curable.²⁶⁹

At the April 7 meeting, ChemImage also requested that Ethicon relinquish its improper claim to ChemImage’s IP.²⁷⁰ Under the Agreement, a *proper* “for cause” termination gave Ethicon an “exclusive, assignment license to the CI Core IP.”²⁷¹ ChemImage made clear that Ethicon did not have a *proper* basis “for cause” termination, and the license to ChemImage’s most valuable IP that came with it.²⁷² Ethicon refused to relinquish the IP.²⁷³

On April 26, 2023, Ethicon formally terminated the Agreement, without affording ChemImage an opportunity to cure.²⁷⁴

D. Ethicon Created A Cloud On ChemImage’s IP, Causing ChemImage To Shut Down

²⁶⁷ P. Treado Aff. ¶¶ 77-78; J. Cohen Aff. ¶ 54.

²⁶⁸ Termination Letter at 2 (emphasis added).

²⁶⁹ PX-181 at 2 (Apr. 10, 2023 email from P. Treado); P. Treado Aff. ¶¶ 77-78; J. Cohen Aff. ¶ 55.

²⁷⁰ J. Cohen Aff. ¶ 56.

²⁷¹ Agreement § 10.3.1.

²⁷² J. Cohen Aff. ¶ 56.

²⁷³ *Id.*

²⁷⁴ J. Cohen Aff. ¶ 57; PX-785 at 1 (May 9, 2023 Letter from J. Cohen regarding Ethicon Notice of Termination of Agreement on Apr. 26, 2023)

In the months following Ethicon’s sudden termination, ChemImage struggled to find another development partner because Ethicon’s pretextual termination meant that ChemImage’s Core IP remained exclusively licensed to Ethicon.²⁷⁵ David Plastino, a valuation expert with decades of experience valuing companies and IP, concluded that ChemImage’s Core IP rights and related know-how and business processes were worth approximately \$109 million as of the date Ethicon purported to terminate the Agreement.²⁷⁶ Ethicon’s “for cause” termination prevented ChemImage from monetizing its technology and rendered those rights essentially worthless.²⁷⁷ Indeed, in May 2023, ChemImage was in talks with Genesis MedTech, Abbvie, Renovo, and Leica, but each of these interested parties backed out when they realized that Ethicon purported to hold an exclusive license to the CI Core IP.²⁷⁸ Ethicon’s pretextual termination prevented ChemImage from partnering with anyone who might compete with Defendants—effectively sidelining ChemImage as competition.

Without the \$40 million termination fee or a new partner, ChemImage was forced to close its doors. In April 2023, ChemImage furloughed its employees. In May 2023, ChemImage laid off the vast majority of its staff and wound down the company’s operations.²⁷⁹

VIII. ETHICON’S TERMINATION WAS PRETEXTUAL

A. Throughout Project Erie, Defendants Acknowledged ChemImage’s Success

Up until its decision to terminate, Defendants expressed enthusiasm about ChemImage’s technology.²⁸⁰ On July 29, 2021, Ethicon presented the ChemImage technology in a live

²⁷⁵ J. Cohen Aff. ¶ 59.

²⁷⁶ D. Plastino Aff. ¶ 4.

²⁷⁷ D. Plastino Aff. ¶ 72.

²⁷⁸ J. Cohen Aff. ¶ 59.

²⁷⁹ J. Cohen Aff. ¶ 61.

²⁸⁰ J. Cohen Aff. ¶ 41; P. Treado Aff. ¶ 40.

demonstration to J&J's Worldwide Chairman and CEO, Alex Gorsky and J&J's Executive Vice President and Worldwide Chairman for MedTech, Ashley McEvoy.²⁸¹ Ethicon reported that J&J's executives asked many questions regarding ChemImage's technology, and the feedback was "very positive."²⁸² Ethicon also noted that the ChemImage program concerned "a higher-risk, higher-reward technology, but the opportunity is tremendous and the work to date is very promising."²⁸³

In mid-2022, Ethicon asked Cambridge to refresh its 2018 assessment of the advanced visualization landscape and to "determine whether alternative technology sources are available or preferred" for Defendants to partner with—other than ChemImage.²⁸⁴ Following its refreshed assessment (known as "Project Fairview"), Cambridge again concluded that there was "*[n]o alternative asset ... as a highly attractive and good fit offering over Erie*, which remains a leading option for Ethicon's ambitious goals in critical structure identification & cancer localization."²⁸⁵

In 2022, J&J executives Peter Shen and Ahmet Tetzl concluded that Project Erie had made significant improvements with "program results now exceeding the thresholds" set by the parties for achieving VAB.²⁸⁶ Defendants' valuation of this success was significant. A June 2022 presentation to J&J Executives stated that Project Erie represented "a significantly *larger* revenue opportunity in the non-robotic laparoscopic visualization market" than forecasted in 2019 and

²⁸¹ See generally, PX-563 (July 23, 2021 email from P. Ritchie and attached presentation).

²⁸² PX-562 at 1 (July 30, 2021 email from P. Treado).

²⁸³ PX-563 at 5 (July 23, 2021 email from P. Ritchie and attached presentation); PX-564 at 1 (Presentation stating "Erie is a High Risk, High Reward Program."); PX-565 at 15 (Presentation stating "Erie technology is the most demanding user of the Athena hardware."); PX-566 at 1 (Jan. 25, 2021 email from P. Ritchie writing, "[w]e've been very consistent from the beginning that this a higher-risk / higher-reward program than usual, and I want to continue to remind people like Peter of the value of doing it, AND the risks.").

²⁸⁴ PX-476 at 3 (Sept. 2022 Summary of Findings and Path Forward Presentation).

²⁸⁵ *Id.* at 6 (emphasis added).

²⁸⁶ PX-315 at 3 (Dec. 2, 2022 Erie Technical Feasibility Update Presentation).

estimated that it could result in “a \$1.1B peak year forecast vs \$0.4B in the 2019 deal model.”²⁸⁷ This was just nine months before Defendants’ purported to terminate the Agreement “for cause.”

Two months after Ethicon received and provided feedback on the Interim VAB Report, Steen Hansen, the technical lead on Project Erie, expressed his enthusiasm for the Project’s potential. Mr. Hansen remarked that his confidence in Project Erie had grown in the six months since he joined the Project, and stated, “Do I think either Ethicon and/or a competitor will create a valuable product using hyperspectral imaging technology in surgery - Yes! Do I think we can evolve the Erie team into delivering such a product - Yes!”²⁸⁸

Likewise, following a November 2022 demonstration of ChemImage’s technology, Ethicon and J&J leadership reported that ChemImage was one of J&J’s “most advanced technologies,” and that they “saw how [ChemImage’s technology] can deliver significant and unique value to [Defendants’] surgeon customers.”²⁸⁹

B. Defendants’ Implemented A Strategy To “Internalize” ChemImage’s Technology

Recognizing the “significant and unique value”²⁹⁰ of ChemImage’s technology, Defendants strategized on how to “internalize” ChemImage’s proprietary model for development in-house. For example, in May 2022, Ethicon’s Rich Gooding asked, “Is it possible that we can do the work of [Project Erie] *on our own* working with fee for service AI vendors like Kitware...?” In response, Ethicon’s then-Project Erie lead, Francesc Fernandez wrote, “*This is something I do*

²⁸⁷ PX-321 at 3 (June 17, 2022 Amendment of Development Agreement with ChemImage Corp. Presentation).

²⁸⁸ See PX-618 at 1 (Nov. 30, 2022 email from S. Hansen to T. Lanier and F. Fernandez).

²⁸⁹ PX-494 at 1 (Nov. 3, 2022 email from R. Gooding).

²⁹⁰ *Id.*

want to explore ... Spending \$10MM+/year to support development efforts is a very expensive proposition.”²⁹¹

Similar conversations continued throughout that summer, when Defendants considered renegotiating the Agreement, and into the fall, when Defendants were discussing how to address budget shortfalls. In a September 2022 email exchange between Mr. Fernandez and Jennifer Kozak (J&J, Business Development) discussing how to address the problem that Ethicon did not “have enough capacity to cover [Project Erie’s] R&D expenses and also milestones should they be met” by ChemImage in 2023,²⁹² Mr. Fernandez proposed that Defendants build their own in-house expertise on machine learning and AI with the help of third party consultants, like Kitware, rather than being locked into a “very expensive” contract, like the Agreement with ChemImage,²⁹³ when Defendants’ robotics budget “likely [could not] support[]” Project Erie in 2023.²⁹⁴

In a separate email to Tamara Lanier and Steen Hansen, Mr. Fernandez again suggested that Defendants “[f]ully internalize feasibility efforts” for ChemImage’s technology, which would require conducting an “IP assessment and ability to use/modify” the Project Erie-related IP in the event “feasibility” was not met by year end and Defendants “terminated” the Project.²⁹⁵ A similar suggestion was made to Hani Abouhalka, J&J MedTech’s Company Group Chairman, Surgery in October 2022, who received an email complaining that “[w]e are paying tons of money” to have

²⁹¹ PX-619 at 2 (May 24, 2022 email from R. Gooding) (emphasis added).

²⁹² PX-309 at 1 (Sept. 15, 2022 email from F. Fernandez).

²⁹⁰ *Id.*

²⁹⁴ PX-316 at 1 (“The resource discussions in your meeting earlier ... is impacting critical programs Jupiter/Athena/Erie and *is not budgeted* ... please be advised that these programs likely can’t be supported as there is no absorption available today”).

²⁹⁵ PX-749 at 2 (Sept. 30, 2022 email from F. Fernandez); *see also* PX-368 at 3 (Feb. 8, 2023 email from F. Haine to A. Tezel and H. Abouhalka with “[i]nternalization of Erie development” identified as one of three “main actions” to “mitigate \$20MM gap in Advanced Visualization”);

“Erie work on all these [AI] algorithms” and proposed as an alternative that J&J “license it today” and instead “shift partnership to [V]erily [Verb] and let Stephen have his [AI] peeps work on the algorithms,” rather than ChemImage.²⁹⁶

In an email sent by Ms. Lanier, on December 19, 2022—just three days after ChemImage submitted its VAB Final Report—Ms. Lanier wrote that given the “[d]esire to keep [the Erie Project] moving” due to the “critical” role it played in J&J’s plans, she and Mr. Fernandez would provide J&J’s executives with a “transition plan” and their perspective on how Defendants could “move towards *internalization* of [Project Erie]” in the first quarter of 2023.²⁹⁷ In a January 2023 email to Rocco De Bernardis, one of J&J’s Executive Sponsors of Project Erie, Ms. Lanier followed up and proposed that J&J “[a]ccelerate *internalization* of the Erie Program” as a way to route more funding to other, higher priority J&J projects.²⁹⁸ Others at Ethicon had suggested a similar approach.²⁹⁹

Defendants followed through on their plan. J&J executive and the Company Group Chairman of Surgery at J&J MedTech, Hani Abouhalka, confirmed that certain “internal teams” from J&J’s MedTech division are currently “working on ... capabilities to help with identifying structures.”³⁰⁰ Defendants’ 30(b)(6) representative, Ms. Lanier, confirmed the same.³⁰¹ On March 18 2024, J&J announced a new partnership with NVIDIA that would “accelerate the delivery of real-time insights at scale to support medical professionals before, during and after procedures”

²⁹⁶ PX-403 (Oct. 26, 2022 email from T. Danowski to H. Abouhalka).

²⁹⁷ PX-312 at 2 (December 19, 2022 email from T. Lanier).

²⁹⁸ PX-754 at 2 (Jan. 13, 2023 email from T. Lanier) (emphasis added)..

²⁹⁹ See, e.g., PX-746 at 4 (Oct. 5, 2021 Skype messages between Ethicon’s Tarik Yardibi writes to J&J’s Breana Roides, in which Mr. Yardibi writes, “we just need to internalize this project[,] hire 10-15 people[,] and] do it ourselves ... would be so much easier”);

³⁰⁰ H. Abouhalka Dep. Tr. at 9:21-10:4, 21:14-22:6.

³⁰¹ T. Lanier Dep. Tr. at 54:17-18.

and allow J&J “to test new AI capabilities for [it’s] connected digital ecosystem for surgery”³⁰²—the *very same digital survey ecosystem* in which ChemImage’s technology was supposed to fit.³⁰³ This NVIDIA partnership seeks to build an “AI model that identifies organs, tissue and potential tumors in real time on an operating room display to support clinical decision-making,” which, as NVIDIA explains, will drive live analytics to help physicians navigate the surgical process.³⁰⁴

C. Defendants Decided To Terminate Before Assessing the VAB Final Report

Tellingly, Defendants had been preparing to terminate the Agreement in favor of their “internalization” strategy for months—even before concluding any formal assessment of the VAB Final Report. Ethicon’s Project Erie Technical Director, Mr. Hansen, testified that, by late January 2023, Ethicon had decided to terminate the Agreement.³⁰⁵ This was confirmed by Ethicon’s outside counsel in this litigation, who represented that on February 2, 2023, Defendants’ in-house attorney, Hilary Reinhardt, “conveyed the termination recommendation” reached by Ethicon’s Project Erie Program Sponsors, including Defendants’ 30(b)(6) representative, Tamara Lanier, and

³⁰² PX-9 (Mar. 18, 2024 NVIDIA article, “Johnson & Johnson MedTech Works With NVIDIA to Broaden AI’s Reach in Surgery”); *see also*, PX-495 (Mar. 18, 2024 article, “Johnson & Johnson MedTech working with NVIDIA to scale AI for surgery”).

³⁰³ PX-358 at 5 (July 20, 2021 Advanced Imaging (Project Zeus) Presentation); PX-590 (Febr. 23, 2020 Top Competitive Scenarios Presentation); PX-591 (Jan. 2022 Project Erie – Regional Alignment Presentation).

³⁰⁴ PX-9 (Mar. 18, 2024 NVIDIA article, “Johnson & Johnson MedTech Works With NVIDIA to Broaden AI’s Reach in Surgery”); *see also*, PX-11 (June 20, 2024 article writing, “Johnson & Johnson MedTech today unveiled Polyphonic™ ..., the open and secure digital ecosystem for a more connected surgical experience. ... In surgery, software solutions that analyze data have the potential to help surgical teams increase collaboration, connect with other experts, and securely share content for greater surgical proficiency.”); PX-495 (Mar. 18, 2024 article, writing “Johnson & Johnson MedTech today announced it is working to accelerate and scale artificial intelligence (AI) for surgery with NVIDIA, supporting increased access to real-time analysis and global availability of AI algorithms for surgical decision-making.”).

³⁰⁵ S. Hansen Tr. at 102:20-106:10 (“Q. I recall earlier ... you mentioned a couple of memos that you prepared in connection with the termination decision and I think you said the first of those was late January. Did I get that right? A. That’s how I remember it, yes.”).

Mr. Fernandez.³⁰⁶ On February 2, Defendants had not even received all of ChemImage’s responses to Ethicon’s ignore label Q&As.³⁰⁷ On February 2, Defendants had not yet received any report on the VAB Final Report or ignore labels from Cambridge.³⁰⁸

Rather, Cambridge issued its first draft report on the use of ignore labels in the VAB Final Report (“Ignore Label Report”) eleven days *after* Defendants decided to terminate the agreement.³⁰⁹ Even that draft report, however, was inconclusive, as Cambridge admitted that its analysis was based only on a “subset of data across studies EL6-8” which “represent[ed] a small fraction of the Erie dataset,” making it “difficult to infer general characteristics of the larger set.”³¹⁰ Cambridge also admitted that it was not possible to determine “the effect of the use of ignore labels ... across the overall dataset” and whether using ignore labels would *improve or degrade* the performance of ChemImage’s model.³¹¹

³⁰⁶ PX-887 at 1; *see also* T. Lanier Dep. Tr. at 275:25-276:7 (“Q. Your counsel this morning stated to us that on February 7th, 2023 Miss Reinhardt sent an invitation to a February 10th, 2023 Teams meeting where Miss Lanier and Mr. Fernandez presented their termination recommendation to the executive sponsors and Miss Reinhardt provided legal advice regarding the termination. Is that consistent with your recollection? A. It is.”).

³⁰⁷ S. Hansen Dep. Tr. at 102:20-105:18.

³⁰⁸ *See* PX-624 (First draft of Independent Review – Ignore Labels Report Presentation, prepared by Cambridge Consultants and dated February 13, 2023); L. Glover Dep. Tr. 17:3-14 (“Q. Do you know when you first began working on the ignore labels report for Ethicon?... A. I would believe it would be around February 2023...”).

³⁰⁹ PX-624 (Feb. 13, 2023 first draft of Independent Review – Ignore Labels Report Presentation, prepared by Cambridge Consultants).

³¹⁰ PX-624 at 7 (Febr. 13, 2023 draft of Independent Review – Ignore Labels Report Presentation, prepared by Cambridge Consultants).

³¹¹ *Id.*; *see also* PX-605 (Dec. 5, 2022 email from Cambridge Consultants’ to Marco Kirstensen and Steen Hansen stating that “Practically ... the only way to verify” the metrics in ChemImage’s forthcoming VAB Final Report would be to “redo the calculations, which doesn’t feel like good value” or engage in a “qualitative exercise that could be done more easily [by] putting side by side scenes with the same metrics and see if any stick out as odd.”).

Even after the Termination Letter was sent on March 6, 2023, Ethicon and J&J continued to work with Cambridge on the draft Ignore Label Report.³¹² Defendants met with Cambridge on a weekly basis to edit the report.³¹³ These meetings included in-house attorney, Hillary Reinhardt (who was personally involved in the decision to terminate) and Christopher Wilds (an attorney from Patterson Belknap who was seconded at J&J at the time).³¹⁴ Throughout this post-Termination Letter editing process, Defendants suggested substantive changes to Cambridge's draft Ignore Label Report.³¹⁵ Together, Defendants and Cambridge worked on the Ignore Label Report through May 2023, *i.e.*, the month *after* Defendants purported to formally terminate the Agreement.³¹⁶ Even after several months of editing, the final Ignore Label Report still came to the same conclusion that Cambridge was unable to determine whether ChemImage's use of ignore labels improved or degraded the use of ChemImage's model because of its limited analysis of data.³¹⁷

³¹² See PX-610 (Mar. 8, 2023 calendar invite from L. Glover regarding "Weekly [Erie] Meeting (Ethicon and CC)").

³¹³ *Id.*

³¹⁴ T. Lanier Dep. Tr. at 207:22-208:5; *see also* PX-871 (LinkedIn Profile of Christopher Wilds showing secondment at J&J from October 2022 to April 2023); PX-416 (Apr. 12, 2023 email from S. Hansen to C. Wilds and H. Reinhardt); PX-887 (Oct. 18, 2024 email from Defendants' attorney, A. Bental, representing that "[o]n February 2, 2023, Hilary Reinhardt ... conveyed the termination recommendation and related legal advice to the [J&J] Executive Sponsors"); PX-185 at 2 (Dec. 21, 2021 email from H. Reinhardt, "Senior Patent Counsel" for "Johnson & Johnson Law Department").

³¹⁵ See, e.g., PX-765 (May 17, 2023 meeting invite from L. Glover to Ethicon regarding "Project Erie – Review of CC's Independent Review – Ignore Labels" writing, "[p]lease find time to review your comments regarding the latest iteration of our report.").

³¹⁶ See PX-478 (May 17, 2023 Independent Review – Ignore Labels Report, prepared by Cambridge Consultants); *see also* L. Glover (Cambridge Consultants' 30(b)(6)) Dep. Tr. at 63:18-64:19.

³¹⁷ PX-477 at 18 (May 17, 2023 Independent Review – Ignore Labels Report, prepared by Cambridge Consultants, stating "The current method of generating performance metrics from scenes with ignore labels...can both improve and degrade the metrics.").

While the Cambridge Ignore Label Report was inconclusive, Ethicon did not even bother to have Cambridge undertake a report analyzing ChemImage’s Final VAB Report (as it had done with M1A and Perfusion).³¹⁸ Cambridge Program Manager, Lee Glover, admitted that “we provided some initial thoughts on the [VAB Final Report] very informally,” but “we didn’t finish or complete or deliver a final report for Milestone 1B.”³¹⁹ Without *any* support from their technical consultant, Defendants still purported to terminate the Agreement “for cause.”

PROPOSED CONCLUSIONS OF LAW

I. ETHICON’S PROCEDURALLY IMPROPER TERMINATION BREACHED THE AGREEMENT

Ethicon does not dispute that the Agreement is a valid and binding contract that imposes limitations on Ethicon’s rights to terminate for cause.³²⁰ Ethicon breached the Agreement in three independent ways.

- *First*, Section 10.3.2(a) does not allow termination “for cause” for purported failure to meet a subset of a Milestone.
- *Second*, Ethicon breached Section 2.4.1(b) of the Agreement when it failed to convene the JSC “to determine whether the Milestones specified in Exhibit B have been met.”
- *Third*, Ethicon violated the cure provision of Section 10.3.1 by preventing ChemImage from curing any purported deficiencies.

None of these independent breaches require the Court to consider evidence related to multispectral imaging, machine learning, or the performance metrics of the VAB Acceptance Criteria. Rather, these are all blatant *procedural* breaches of the Agreement’s termination, notice,

³¹⁸ L. Glover Dep. Tr. at 80:20-23 (“Q. Do you know whether Cambridge Consultant did in fact complete an evaluation of the M1B final report? A. I don’t believe we did.”).

³¹⁹ L. Glover Dep. Tr. at 9:16-21; 76:12-4; 79:11-81:6

³²⁰ See Proposed Joint Pre-trial Order, Parties’ Stipulated Facts, at ¶¶ 4-5 (“On December 27, 2019, Ethicon and ChemImage entered into the...Agreement” and “The Agreement... is a valid and enforceable contract.”); Lanier Dep. 129:3-129:17 (testimony from Defendants’ 30(b)(6) witness acknowledging that “Ethicon had to provide written notice” and an “opportunity to cure” before terminating for cause).

and cure provisions, supported by undisputed facts. If the Court finds that any of these constitute a breach of the Agreement, the only issue for trial on Plaintiff's contract claim is the appropriate measure of ChemImage's damages, including declaratory judgment and attorneys' fees.³²¹

A. The Agreement Does Not Allow Termination “For Cause” For Failure To Meet A Subset Of A Milestone

The Agreement provides only one basis for Ethicon to terminate “for cause,” that is: “CI’s failure, subject to the cure provisions of Section 10.3.1, to achieve a Development Milestone as described in Exhibit B.”³²² Critically, the Agreement does not contain any provision that allows Ethicon to terminate “for cause” based on ChemImage’s purported failure to meet a *partial* Milestone or a *subset* of a Milestone. Rather, Exhibit B of the Agreement defines M1B as demonstrating “[s]uccessful in vivo Demonstration with Modified JNJ Visualization System for Critical Structures Identification Functionality - \$2,500,000.”³²³ The M1B description that follows in Exhibit B-1, requires detection of five critical structures: (1) Ureter, (2) Nerve, (3) Veins or (4) Arteries (described with veins as “Vessels”), and (5) Bile Duct.³²⁴

For its part, ChemImage was prepared to test its technology against all five critical structures. But, at *Defendants’* request, ChemImage prioritized work on a VAB-only subset of M1B, with “Ureter and Nerve feasibility efforts” to be postponed “until 2023.”³²⁵ After requesting that ChemImage submit a Final Report on VAB only, Ethicon sent ChemImage a Termination

³²¹ ChemImage also asserts a claim for tortious interference, which would proceed to trial on a narrower set of facts against Johnson & Johnson only.

³²² Agreement § 10.3.2(a). *See also* FOF *supra*, Section IV.D.1.

³²³ Agreement, Exhibit B at 56.

³²⁴ Agreement, Exhibit B at 62.

³²⁵ *See* FOF *supra* Section VII.A; *see also* PX-280 at 2 (July 8, 2022 email from P. Ritchie); *see also* P. Treado Aff. ¶ 44; PX-784 at 10 (Sept. 21, 2021 JSC Meeting 8) (by September 2021, Ethicon was considering splitting M1B into veins, arteries, and perfusion (PVA) and pushing out work on bile ducts, ureters, and nerves (UBN)).

Letter purporting to terminate the Agreement “for cause.”³²⁶ In that letter, Ethicon recognized that the termination was premised on “a final report provided on December 16, 2022, for a *subset* of the critical structures, veins, arteries, and bile ducts (collectively, “VAB”) that are a *part of* Milestone 1B in the Agreement.”³²⁷ Ethicon’s attempt to terminate “for cause” for a purported failure of a *subset* of M1B violated Section 10.3.2(a) of the Agreement.

Internally, Ethicon had already recognized that it could not terminate “for cause” based on a partial failure of a milestone. It repeatedly discussed making revisions to the Agreement to add “checkpoints at which Ethicon has [the] option to partially terminate efforts on individual targets [if] minimum milestone criteria are not achieved by target date.”³²⁸ For example, at one point, Ethicon wanted to be able to “terminate agreement” if success with a subset of M1B, “PVA” (perfusions, veins, and arteries) was “not achieved” by a certain date.³²⁹ And Ethicon contemplated giving itself a right to “terminate the agreement completely right away” if ChemImage failed to meet a “checkpoint” at a subset of M1B.³³⁰ J&J leadership, however, rejected those proposed amendments and those provisions did *not* become part of the Agreement.³³¹ The plain language of the Agreement does not permit termination for failure to meet a subset of a milestone—only failure to “achieve a Development Milestone.”³³² *See also Universal Instruments*

³²⁶ Termination Letter at 2.

³²⁷ Termination Letter at 2.

³²⁸ PX-810 at 7 (June 6, 2022 email from R. Gooding).

³²⁹ PX-577 (Proposed Revisions to the Erie RDLC Agreement).

³³⁰ PX-810 at 7 (June 6, 2022 email from R. Gooding).

³³¹ *See generally* Agreement; *see also* PX-280 at 2 (July 7, 2022 email from R. Gooding, writing “we are providing a revised recommendation to not pursue approvals for renegotiation of the agreement at this time...”).

³³² Agreement § 10.3.2.

Corp. v. Micro Sys. Eng'g, Inc., 924 F.3d 32, 41 (2d Cir. 2019) (contract “must be enforced according to the plain meaning of its terms”).

Ethicon will attempt to argue that if—in its sole view—the VAB portion of M1B was not achieved, the entirety of M1B could never be achieved. However, Section 2.4.1(b) of the Agreement empowered only the jointly convened JSC to make that determination, as explained *infra* in Section B. Further, such an argument, based entirely on speculation (and unsupported by any expert testimony), would be futile considering that the Agreement prescribed no deadlines by which M1B—or any Milestone—had to be met.³³³ In other words, the Agreement afforded ChemImage additional time to attempt to cure purported VAB deficiencies (*see* Section 10.3.1), *and* to attempt the remaining Nerves and Ureter portions of M1B (*see* Agreement, fixing no deadlines for the achievement of Milestones).

B. Ethicon’s Failure To Convene The Joint Steering Committee Breached Section 2.4.1(b) of the Agreement

“[F]ailure to effect termination according to the terms of a contract constitutes a breach.” *Raviv v. Mirror Biologics, Inc.*, 2024 WL 2798870, at *18 (S.D.N.Y. May 31, 2024). The Agreement allows a “for cause” termination for only one reason: “failure, subject to the cure provisions of Section 10.3.1, to achieve a Development Milestone.”³³⁴ Critically, the Agreement vests only one entity with authority to determine whether a Development Milestone has been achieved: the Joint Steering Committee (“JSC”), composed of both ChemImage and Ethicon representatives.³³⁵ “When a contract’s terms include a procedure for termination, here applicable New York law demands strict compliance with that procedure.” *Brueckner v. You Can*

³³³ Agreement, Ex. B-1, at 4-15.

³³⁴ Agreement § 10.3.2.

³³⁵ Agreement § 2.4(b)

Beam LLC, 2021 WL 2158733, at *4 (S.D.N.Y. May 27, 2021); *Black River Plumbing, Heating and Air Cond., Inc. v. Bd. of Ed. Thousand Islands Cent. Sch. Dist.*, 175 A.D.3d 1051, 1052 (4th Dep’t 2019) (same). It is undisputed that Ethicon never convened the JSC to determine whether ChemImage had met Milestone 1B before purporting to terminate on that basis.³³⁶ In fact, at the JSC’s sole meeting post-dating submission of the VAB Final Report, Ethicon explained it was not prepared to discuss the Final Report, and thereafter cancelled future meetings of the JSC that had been requested by ChemImage.³³⁷ Because Ethicon purported to terminate “without following the contractual procedures, the termination was invalid and breached” the Agreement. *Gulf Ins. Co. v. Fidelity & Deposit Co.*, 16 Misc. 3d 1116, at *4 (N.Y. Sup. Ct. 2007); *see also, e.g., Brueckner*, 2021 WL 2158733, at *4-6 (granting summary judgment of breach when party failed to “follow[] the termination process it agreed to”); *O’Brien & Gere, Inc. of N. Am. v. G.M. McCrossin, Inc.*, 148 A.D.3d 1804, 1805-06 (4th Dep’t 2017) (similar) *Morris v. Lee*, 2011 WL 721663, at *4 (S.D.N.Y. Feb. 24, 2011) (similar).

Ethicon will argue that its unilateral rejection of ChemImage’s VAB Final Report rendered the JSC’s determination of ChemImage’s ability to meet M1B a *fait accompli*. This argument, however, ignores both the well-settled law as set forth in *Brueckner* as well as the Agreement’s “Deadlock” provision.³³⁸ When a contract requires a party to go through a specific process to deem its counterparty’s performance deficient, it breaches the contract when it fails to go through

³³⁶ See FOF *supra* Section VI.C; *see also* P. Treado Aff. ¶ 69 (ChemImage requested a JSC meeting to evaluate the Milestone 1B Final Report and Ethicon refused to convene); PX-811 (Mar. 7, 2023 email from F. Fernandez declining JSC meeting invitation); PX-587 (Mar. 7, 2023 email from D. Denys regarding T. Lanier and F. Fernandez declining JSC meeting invitation).

³³⁷ *Id.*

³³⁸ See Agreement § 2.4.3 which provides, in relevant part, that “[i]n the event a deadlock occurs ... the JSC shall attempt to resolve such deadlock for a period of thirty (30) days by engaging in good faith discussions” followed by an escalation procedure and additional fifteen (15) days of discussion.

with that process, *regardless* of whether the counterparty’s performance is “allegedly defective or nonconforming.” *See, e.g., Mike Bldg. & Contracting, Inc. v. Just Homes, LLC*, 27 Misc. 3d 833, 844-45 (N.Y. Sup. Ct. 2010) (party breached contract by terminating without required certification, even though counterparty’s work was deficient and bills were exaggerated); *Gen. Supply & Const. Co. v. Goelet*, 241 N.Y. 28, 33-34 (1925) (“Though [defendant] may have been justified ... in his belief that the [plaintiff] would not ... finish the work within a reasonable time, yet ... he could not rescind the contract for that reason, except according to its terms.”). “Even if good cause existed”—that is, even if ChemImage had failed to reach a milestone—“[Ethicon] was required to obtain” the JSC’s determination that a milestone had not been reached to show “there was in fact good cause to terminate the contract.” *Morris*, 2011 WL 721663, at *5. Its failure to do so was a breach. *See id.* (granting summary judgment).

Any claim of the JSC’s futility is also inconsistent with the plain terms of the contract. The Agreement expressly contemplated that a JSC composed of two members from ChemImage and two from Ethicon might inevitably become deadlocked, and outlined a detailed procedure for resolving the deadlock. If the committee became deadlocked with respect to a matter that might require “modification of the Development Plan” (such as failure to meet a milestone leading to program termination) the JSC was directed first “to attempt to resolve such deadlock” through “good faith discussions” for a period of thirty days.³³⁹ If the disagreement persisted, Ethicon’s Head of Digital Surgery and ChemImage’s CEO were to try to solve the problem for an additional fifteen days.³⁴⁰ And if the parties still could not resolve the deadlock, they were then to “refer the

³³⁹ Agreement § 2.4.3(b).

³⁴⁰ Agreement § 2.4.3(b).

unresolved matter for binding arbitration” if desired.³⁴¹ These procedures provided a route for speedy resolution, through binding arbitration, of any issues the parties could not resolve on their own. By refusing to convene the JSC in accordance with Section 2.4.1(b), Ethicon not only breached the Agreement but also robbed ChemImage of the opportunity to pursue the deadlock resolution process for which it contracted in Section 2.4.3(b).

C. Ethicon Violated Section 10.3.1 By Preventing ChemImage From Curing

Before terminating the Agreement for cause, Ethicon was required to (1) give ChemImage “a written notice” which “specifies in reasonable detail the nature of the breach or default,” and (2) afford ChemImage at least thirty days to cure the breach, with more time allowed “if the breach or default is not reasonably capable of being cured” within that time.³⁴² Those notice-and-cure requirements are “fully enforceable,” *USI Ins. Servs. LLC v. Miner*, 801 F. Supp. 2d 175, 181 (S.D.N.Y. 2011), and “terminating a contract without complying with the notice and cure provisions therein is itself a material breach.” *In re 4Kids Ent., Inc.*, 463 B.R. 610, 683 (Bankr. S.D.N.Y. 2011). Ethicon’s purported termination failed to comply with both requirements.

1. Ethicon Refused To Provide “Reasonable Detail” That Would Allow ChemImage To Cure

First, Ethicon failed to give ChemImage a “written notice” that “specifies in reasonable detail the nature of the breach or default” as required by § 10.3.1. That provision of the Agreement calls for Ethicon to “identify the alleged breach with enough specificity to give [ChemImage] a fair opportunity to cure and receive the fair benefits of its bargain.” *Core Sec. SDI Corp. v. Albany Med. Ctr.*, 2019 WL 1228550, at *2 (N.D.N.Y. Mar. 15, 2019). Ethicon’s March 6, 2024

³⁴¹ Agreement § 2.4.3(b).

³⁴² Agreement § 10.3.1.

Termination Letter—the only purported “written notice” it ever gave ChemImage—did not meet that standard.³⁴³ Critically, the lack of “reasonable detail” in the Termination Letter prevented ChemImage from curing.

The Termination Letter asserted three reasons that Ethicon believed ChemImage’s VAB Final Report failed to achieve Milestone 1B: “[1] uncertainty with respect to negative controls, [2] use of omnipresent ignore labels, and [3] data discrepancies between a preliminary report and the final report.”³⁴⁴ As explained by ChemImage to Ethicon in its March 17 letter, and at the Parties’ April 7 meeting, these sparse descriptions did not give ChemImage notice adequate to afford it a “fair opportunity to cure” these alleged breaches.³⁴⁵ *Core Sec. SDI*, 2019 WL 122850, at *2.

Ethicon steadfastly refused to provide any information that would allow ChemImage to cure and thereby failed “to provide [ChemImage] with sufficient ‘reasonable detail’” of its breach, and thus violated the Agreement.³⁴⁶ *Ballard v. Parkstone Energy, LLC*, 664 F. Supp. 2d 325, 329-330 (S.D.N.Y. 2009); *see also, e.g., New Image Constr., Inc. v. TDR Enters., Inc.*, 74 A.D.3d 680, 681-82 (1st Dep’t 2010) (defendant breached contract by failing to comply with notice provision); *MCK Bldg. Assocs. v. St. Lawrence Univ.*, 301 A.D.2d 726, 727-28 (3d Dep’t 2003) (similar).

2. Ethicon Prevented ChemImage From Curing

Second, Ethicon also failed to respect the Agreement’s mandatory cure period and, in fact, actively prevented ChemImage’s attempts to cure the alleged breaches. “[A] party” like Ethicon that “disrupts and frustrates the other’s performance breaches the underlying agreement.” *St.*

³⁴³ See FOF *supra* Section VII.B and C; *see also* J. Cohen Aff. ¶¶ 54-55; P. Treado Aff. ¶ 69.

³⁴⁴ See FOF *supra* Section VII.B

³⁴⁵ See FOF *supra* Section VII.C; *see also* J. Cohen Aff. ¶ 54; P. Treado Aff. ¶¶ 75-78..

³⁴⁶ See FOF *supra* Section VII.C.

Christopher’s, Inc. v. JMF Acq., LLC, 2021 WL 6122674, at *4 (2d Cir. 2021). Each of the purported problems pointed to by Ethicon in its Termination Letter relates to data collection, which was a joint effort between the Parties.³⁴⁷ Indeed, the Termination stated that in order to address Ethicon’s purported concerns, “previously completed labs, data collection, and annotation processes would need to be **reworked and repeated**.”³⁴⁸

In fact, ChemImage already had numerous additional labs planned at J&J facilities when Ethicon terminated the Agreement.³⁴⁹ Defendants then **cancelled** these already scheduled labs and **refused** to schedule other labs or meetings between the Parties to discuss the Development Plan.³⁵⁰ Because Project Erie Labs were conducted at J&J-owned and operated facilities, with Ethicon veterinary surgeons, Defendants’ cancellations made it impossible for ChemImage to undertake any “data collection” based cure.³⁵¹

This is a textbook violation of the prevention doctrine: Ethicon “unjustly prevented” ChemImage from curing its default, and should not be “permitted to take advantage of its own wrong.” *In re Bankers Tr. Co.*, 450 F.3d 121, 128-29 (2d Cir. 2006). “Numerous courts in this District have applied the prevention doctrine” to uphold claims against defendants like Ethicon that “actively sought to hinder” the plaintiff’s ability to cure a claimed breach. *Pac. Life Ins. Co.*

³⁴⁷ See FOF *supra* Section VII.B; see also A. Saltman Aff. ¶¶ 12-16, 26-28, 30, 32, 35-36.

³⁴⁸ See FOF *supra* Section VII.B.

³⁴⁹ Including three labs scheduled in February and March 2023 for the express purpose of *inter alia* “PVAB [perfusion, veins, arteries, and bile ducts] gap data collection.” See J. Cohen Aff. ¶ 57; PX-30 (Dec. 2, 2022 email attaching Erie Program Plan 2023, dated Dec. 1, 2022) at 7; see also FOF *supra* Section VII.B.

³⁵⁰ See FOF *supra* Section VII.B; see also PX-41 (Feb. 27, 2023 email from T. Lanier to ChemImage personnel asking to cancel the upcoming JSC meeting); PX-587 (Mar. 7, 2023 email from C. Denys regarding Ethicon’s T. Lanier and F. Fernandez declined the JSC meeting scheduled for that day); see also PX-811 (Mar. 7, 2023 email from F. Fernandez declining JSC meeting invitation); PX-615 (Feb. 9, 2023 email from F. Fernandez to ChemImage cancelling the scheduled EL).

³⁵¹ See FOF *supra* Section VII.B.

v. U.S. Bank Nat'l Ass'n, 636 F. Supp. 3d 366, 424 (S.D.N.Y. 2022) (collecting cases). ChemImage was “ready and willing” to recollect and rework the data Ethicon demanded—*if* it were actually necessary—but J&J “refused [ChemImage] further access to the” laboratories necessary to carry out the work, and so “frustrated” and “prevented” ChemImage’s performance. *Hidden Meadows Dev. Co. v. Parmelee’s Forest Prods., Inc.*, 289 A.D.2d 642, 644 (3d Dep’t 2001); *see also, e.g., Bast Hatfield, Inc. v. Joseph R. Wudnerlich, Inc.*, 78 A.D.3d 1275-76 (3d Dep’t 2010) (party’s performance was “frustrated” when it “was prevented from accessing its work area”). In fact, Ethicon had “an affirmative obligation to help facilitate [ChemImage’s] performance.” *Ixe Banco, S.A. v. MBNA Am. Bank, N.A.*, 2008 WL 650403, at *10 (S.D.N.Y. Mar. 7, 2008). Instead, Ethicon went out of its way to hinder a cure. That “constitutes a breach” on Ethicon’s part, and “excuses performance” of the cure by ChemImage. *Osinoff v. Opera Sols LLC*, 2017 WL 5900297, at *4 (S.D.N.Y. Nov. 14, 2017).

Ethicon also failed to fulfill even its more basic obligation to give ChemImage an adequate amount of time to cure. Under the Agreement, ChemImage was entitled to the time it needed to “diligently prosecute the cure to completion” even if that took longer than 30 days.³⁵² Ethicon nonetheless purported to terminate the agreement on April 26, 2024, before any cure could be completed. That too breached the contract. *See, e.g., Thousand Islands*, 175 A.D.3d at 1052 (granting summary judgment of breach because “defendants’ failure to allow plaintiff the requisite time to cure before terminating the contract rendered defendants’ termination wrongful”); *Filmline (Cross-Country) Prods., Inc. v. United Artists Corp.*, 865 F.2d 513, 518 (2d Cir. 1989) (failure to afford opportunity to cure breached contract).

³⁵² Agreement § 10.3.1.

Finally, to the extent Ethicon argues it was excused from providing adequate notice and an opportunity to cure because doing so would be futile, “New York law strictly limits the ‘futility exception’” to notice-and-cure requirements “to situations in which the breaching party *expressly disavows* any further duties or abandons performance.” *In re Best Payphones, Inc.*, 2007 WL 1388103, at *6 (Bankr. S.D.N.Y. May 8, 2007), *aff’d*, 432 B.R. 46 (S.D.N.Y. 2010), *aff’d*, 450 F. App’x 8 (2d Cir. 2011); *see also, e.g., Morris*, 2011 WL 721663, at *4 (“Even where it seems that a contractor will not cure its apparent breach or finish a project within a reasonable time, absent abandonment of the project, the contract may only be terminated according to its terms.”). To the contrary, ChemImage *expressly avowed* in its March 17 correspondence that it was ready to cure, and tried multiple times to obtain relevant details to effectuate a cure (to the extent necessary) but was prevented from doing so.³⁵³ In any event, Ethicon’s failure to give ChemImage adequate notice of the breach, and their active prevention of ChemImage’s attempts to cure it, foreclose any reliance on the futility exception as Ethicon is “not permitted to take advantage of its own wrong.” *Bankers Tr.*, 450 F.3d at 128-29.

II. ETHICON’S SUBSTANTIVELY IMPROPER TERMINATION BREACHED THE AGREEMENT

Even if the Court finds that Ethicon’s termination was not procedurally improper, it was substantively improper because each of the three purported bases in the Termination Letter fail: “[1] uncertainty with respect to negative controls, [2] use of omnipresent ignore labels, and [3] data discrepancies between a preliminary report and the final report[.]”³⁵⁴

³⁵³ *See supra* Sections VII.C, VI.C; PX-172 (July 19, 2023 email from J. Cohen attaching ChemImage letter responding to Ethicon’s Notice of Material Breach and Intent to Terminate dated March 17, 2023); parties had a meeting in Atlanta on April 7, 2023, *see* PX-777 (Apr. 10, 2023 email from P. Treado attaching his notes from the April 7, 2023 meeting); *see also* J. Cohen Aff. ¶ 52; P. Treado Aff. ¶¶ 74-75.

³⁵⁴ *See* Termination Letter at 2.

First, the plain language of the VAB Acceptance Criteria makes clear that the only requirement for use of negative control scenes, was that it reached “10% (of total demonstrated N) to detection scenes.”³⁵⁵ The negative control scenes are otherwise governed by the same performance criteria generally applicable under the VAB Acceptance Criteria (*i.e.*, 80% sensitivity and specificity, etc.). Although the Termination Letter is silent as to how ChemImage purportedly violated this criteria, Defendants’ clinical expert, Dr. Estape, identified one negative control scene that he believed was not actually a negative control.³⁵⁶ But even if ChemImage were to remove that purportedly flawed negative control scene, ChemImage would *still* meet the 10% threshold required by the VAB Acceptance Protocol, and ChemImage would *still* have demonstrated the performance required under the Acceptance Criteria.³⁵⁷ Moreover, additional negative control scenes could have easily been collected, had Defendants not cancelled upcoming labs.³⁵⁸

Second, the DRB approved ChemImage’s use of ignore labels *and* plain language of the VAB Acceptance Criteria makes clear that there was no quantitative limit on the use of ignore labels.³⁵⁹ Ethicon’s complaint of “omnipresent” ignore labels is untethered to any contractual requirement to use a particular number of labels.³⁶⁰ Defendants’ machine learning expert, Dr.

³⁵⁵ See VAB Final Report at 17.

³⁵⁶ See R. Estape Expert Report ¶¶ 104-105.

³⁵⁷ See VAB Final Report at 17.

³⁵⁸ See PX-615 at 2 (Feb. 6, 2023 email from Tamara Lanier to ChemImage cancelling the next week’s Ureter Nerve lab); PX-41 (Feb. 27, 2023 email from Tamara Lanier to ChemImage personnel asking to cancel the upcoming JSC meeting); PX-587 (Mar. 7, 2023 email from C. Denys stating that Ethicon’s T. Lanier and F. Fernandez declined the JSC meeting scheduled for that same day); PX-811 (Mar. 7, 2023 email from F. Fernandez declining the Mar. 7, 2023 JSC meeting); *see also* D. Sodickson Aff. ¶ 176.

³⁵⁹ See VAB Final Report at 17.

³⁶⁰ *Id.*

Hannaford, confirmed this.³⁶¹ To the extent Ethicon’s vague complaint of “omnipresent ignore labels” reflects concern over ChemImage’s treatment of ignore labels in its model, this is easily adjusted—a cure that ChemImage undertook but Ethicon refused to consider.³⁶² Notably, Ethicon did not otherwise identify any way in which ChemImage’s use of ignore labels was contrary to the DRB’s directives on such use and related JSC determinations.

Third, Ethicon does not identify any specific “data discrepancies between [the] preliminary report and the final report” in the Termination Letter.³⁶³ However, Defendants’ 30(b)(6) designee, Dr. Hansen, testified that this purported “discrepancy” was limited to one instance: the editing of a slide from the Interim VAB Report to the Final VAB Report, to include a different example of a negative control scene.³⁶⁴ The purported “discrepancy” in this single edit is untethered to any contractual requirement to use specific examples of negative control scenes, or to refrain from making changes from the Interim to Final Reports. Further, this single edit cannot reasonably support Ethicon’s conclusion that the VAB Final Report is, in its entirety, “unevaluable.”³⁶⁵ Moreover, as explained above, even if ChemImage removed (rather than replaced) this single negative control scene from the VAB Final Report, it would *still* meet the 10% threshold required by the VAB Acceptance Protocol.³⁶⁶

³⁶¹ See B. Hannaford Dep. Tr. 89:19-90:12 (“So other than the joint data exclusion and inclusion and other than the ignore label criteria that we looked at..., there is no other guidance here with respect to ignore labels in the acceptance protocol correct....The acceptance criteria doesn’t prescribe any particular amount of ignore labels that may or may not be used subject to these two conditions, correct? A. I don’t see a number there.”).

³⁶² See PX-181 at 2-3 (Apr. 10, 2023 email from P. Treado); P. Treado Aff. ¶¶ 71-73; J. Cohen Aff. ¶¶ 51-52.

³⁶³ For the reasons set forth in ChemImage’s Motion in Limine, Dkt. 126, any attempt by Ethicon to supplement its Termination Letter with new bases should be precluded at trial.

³⁶⁴ S. Hansen Dep. Tr. 123:5-125:11.

³⁶⁵ See Termination Letter at 2.

³⁶⁶ See VAB Final Report at 17.

Finally, although not raised in the Termination Letter (and therefore not appropriate for trial, *see* ChemImage’s Motion in Limine), Defendants’ post-Termination arguments related to low sample size and obscuration depth also fail. Critically, the VAB Acceptance Criteria, does **not** prescribe any required sample size (also referred to as an “N” value), let alone any required sample size at particular obscuration depths.³⁶⁷ Defendants’ machine learning expert, Dr. Hannaford, confirmed this.³⁶⁸ And even if it did, ChemImage could have easily obtained additional samples at greater obscuration depths had Defendants not cancelled additional labs.³⁶⁹

III. J&J TORTIOUSLY INTERFERED WITH THE RELATIONSHIP BETWEEN CHEMIMAGE AND ETHICON

To sustain a claim of tortious interference with contract under New York law, ChemImage must prove: “(1) the existence of a valid contract between the plaintiff and a third party, (2) defendant’s knowledge of the contract, (3) defendant’s intentional inducement of the third party to breach the contract or otherwise render performance impossible, (4) an actual breach of the contract, and (5) damages to the plaintiff.” *Rep. of Turkey v. Christie’s, Inc.*, 316 F. Supp. 3d 675, 678 (S.D.N.Y. 2018). The facts at trial will demonstrate that J&J tortiously interfered in the contractual relationship between Ethicon and ChemImage.

A. The Agreement Is A Valid And Binding Contract

³⁶⁷ *Id.*; *see also*, PX-769 at 110 (Aug. 25, 2022 Data Review Board Meeting 5 Presentation, instructing to “[u]se **average** to classify degree of obscuration” when reporting results, rather than any required sample size at particular obscuration depths) (emphasis added).

³⁶⁸ B. Hannaford Dep. Tr. 85:3-5 (“Q. The acceptance criteria does not prescribe any necessary sample size, correct? A. Not with a number, correct.”).

³⁶⁹ *See* PX-615 at 2 (Feb. 6, 2023 email from Tamara Lanier to ChemImage cancelling the next week’s Ureter Nerve lab); PX-41 (February 27, 2023 email from Tamara Lanier to ChemImage personnel asking to cancel the upcoming JSC meeting); PX-587 (March 7, 2023 email from C. Denys stating that Ethicon’s T. Lanier and F. Fernandez declined the JSC meeting scheduled for that same day); PX-811 (March 7, 2023 email from F. Fernandez declining the March 7, 2023 JSC meeting); *see also* D. Sodickson Aff. ¶ _.

First, Ethicon does not dispute that it signed the Agreement in late 2019 and that Ethicon and ChemImage are bound by its terms.³⁷⁰ The first element is met. *Infanti v. Scharpf*, 570 F. App'x 85, 5 (2d Cir. 2014) (“To state a viable claim for tortious interference with contract, a plaintiff must establish the existence of a valid contract between the plaintiff and a third party.”) (internal quotation marks and citation omitted).

B. J&J Had Knowledge Of The Agreement

Second, the record is replete with evidence that J&J had knowledge of the Agreement. “A plaintiff asserting a tortious interference claim under New York law must prove that the defendant had ‘actual knowledge’ of the breached contract.” *Reach Music Publ’g, Inc. v. Warner Chappell Music, Inc.*, 988 F. Supp. 2d 395, 402 (S.D.N.Y. 2013). The defendant need not be aware of “all the details of a contract”, *see Medtech Prods. Inc. v. Ranir, LLC*, 596 F. Supp. 2d 778, 796 (S.D.N.Y. 2008), but must possess “knowledge of the contract’s existence.” *Deangelis v. Corzine*, 998 F. Supp. 2d 157, 186 (S.D.N.Y. 2014) (internal citations and quotations omitted).

J&J was more than “aware” of the Agreement.³⁷¹ At least three J&J executives, including J&J’s CEO, “ha[d] to sign off on the agreement itself.”³⁷² And Ethicon needed to “align” with Ashley McEvoy, J&J’s then-Worldwide Executive Vice President, to amend the agreement.³⁷³ Further, J&J announced publicly in October 2020 that it was “very excited about [the] collaboration with ChemImage” and had “facilitated the collaboration with [its] Ethicon surgery

³⁷⁰ See T. Lanier Dep. Tr. at 16:19-23; Proposed Joint Pre-trial Order § IX, Parties’ Stipulated Facts, at ¶¶ 4-5 (“On December 27, 2019, Ethicon and ChemImage entered into the...Agreement” and “The Agreement... is a valid and enforceable contract.”).

³⁷¹ See FOF *supra* Section III-IV; P. Shen Dep. Tr. 38:8-18.

³⁷² See FOF *supra* Section III)-IV; T. Lanier Dep. Tr. 26:6-20.

³⁷³ See FOF *supra* Section III-IV; P. Shen Dep. Tr. at 105:13-106:8.

business.³⁷⁴ The second element is therefore met. *See Fly Shoes s.r.l. v. Bettye Muller Designs Inc.*, 2015 WL 4092392, at *11 (S.D.N.Y. July 6, 2015) (upholding tortious interference claim where “[t]here can be no question that [Defendant] knew of that contract.”); *Hidden Brook Air, Inc. v. Thabet Aviation Int’l*, 241 F. Supp. 2d 246, 279-80 (S.D.N.Y. 2002) (finding a third party had actual knowledge of a contract between plaintiff and defendant after examining evidence in the record).

C. J&J Intentionally Induced Ethicon’s Breach And Rendered Performance Impossible

Third, the evidence at trial will show that J&J “intentionally and through improper means induced the breach” of the Agreement. *WFB Telecomm. v. NYNEX Corp.*, 590 N.Y.S.2d 460, 461 (1st Dep’t 1992).

As a threshold matter, J&J executives considered—but rejected—amending the Agreement to allow Ethicon to terminate “for cause” based on purported failure to reach only a subset of a Milestone.³⁷⁵ J&J’s in-house counsel, Hillary Reinhardt, nevertheless advised Ethicon to proceed with its improper termination.³⁷⁶ And J&J executives, “Rocco De Bernardis, Jennifer Kozak, and Ahmet Tezel approved the decision to terminate.”³⁷⁷

The intentional and improper nature of J&J’s directive to Ethicon to breach the Agreement is further underscored by the fact that J&J knew that ChemImage’s technology was valuable³⁷⁸

³⁷⁴ See PX-484 (Oct. 14, 2020 J&J Innovation podcast transcript).

³⁷⁵ See FOF *supra* Section VII(A).

³⁷⁶ T. Lanier Dep. Tr. at 207:22-208:5; *see also*, PX-871 (LinkedIn Profile of Christopher Wilds showing secondment at J&J from October 2022 to April 2023); PX-416 (Apr. 12, 2023 email from S. Hansen to C. Wilds and H. Reinhardt); PX-185 at 2 (Dec. 21, 2021 email from H. Reinhardt, “Senior Patent Counsel” for “Johnson & Johnson Law Department”).

³⁷⁷ T. Lanier Dep. Tr. 130:10-131:5.

³⁷⁸ See FOF *supra* Section VIII(A); PX-618 at 1 (November 30, 2022 email from S. Hansen).

and sought to internalize development of its multispectral imaging technology, without ChemImage.³⁷⁹ In December 2022, Ms. Lanier expressed a “[d]esire to keep [the Erie Project] moving” due to the “critical” role it played in J&J’s plans.³⁸⁰ In fact, throughout the partnership with ChemImage, J&J made plans to “internalize” ChemImage’s technology and continue developing it through other projects. The record contains multiple examples of J&J’s efforts to “internalize” the Erie technology for its own benefit:

- In October 2021, Tarik Yarbidi, a Director of Data Science and Digital health at J&J, discussed “internaliz[ing the] project” and “do[ing] it ourselves[;]”³⁸¹
- In May 2022, Steen Hansen (J&J’s Senior Research & Development Manager) and Tarik Yarbidi discussed combining Project Erie’s “algorithm expertise” and “hardware expertise” with a Tesla project, an internal development initiative at J&J unrelated to Project Erie;³⁸²
- In August 2022, Steen Hansen was charged with the task of “prepar[ing] slides supporting the case to internalize Erie development[;]”³⁸³
- In December 2022, J&J was actively brainstorming how to “move towards internalization of” Project Erie;³⁸⁴

³⁷⁹ See FOF *supra* Section VIII(B).

³⁸⁰ See FOF *supra* Section VIII(B); PX-312 at 2 (Dec. 19, 2022 email from T. Lanier).

³⁸¹ See FOF *supra* Section VIII(B); PX-746 at 5 (Oct. 5, 2021 Slack messages between B. Roides and T. Yarbidi).

³⁸² See FOF *supra* Section VIII(B); PX-747 at 1 (May 6, 2022 Slack messages between S. Hansen and T. Yarbidi).

³⁸³ See FOF *supra* Section VIII(B); PX-748 at 1 (Aug. 10, 2022 email from F. Fernandez).

³⁸⁴ See FOF *supra* Section VIII(B); PX-312 at 2 (Dec. 19, 2022 email from T. Lanier).

- By January 2023, J&J sought to “explore accelerating internalization of ChemImage’s work” to save money.³⁸⁵

On March 18, 2024, J&J announced a partnership with NVIDIA on a venture similar to Project Erie that aimed to “scale AI for surgery.”³⁸⁶ J&J’s partnership with NVIDIA purports to create a “digital ecosystem” that mirrors Project Erie.³⁸⁷

The evidence at trial will establish that J&J directed Ethicon to terminate its partnership with ChemImage while using the “for cause” termination to tie up ChemImage’s core IP to prevent it from falling into the hands of a competitor.³⁸⁸ J&J therefore acted intentionally and maliciously to sideline ChemImage while advancing own internal critical structure detection program at ChemImage’s expense.³⁸⁹

New York courts have found tortious interference with a contract where, as here, a parent acted maliciously in directing its subsidiary to breach its contract with a third party. *See U.S. Fidelity & Guar. Co. v. Petroleo Brasileiro S.A.-Petrobras*, 2001 WL 300735, at *24 (S.D.N.Y. Mar. 27, 2001) (noting that a plaintiff may show “malice” in order for courts to find that a parent corporation tortiously interfered with a contract entered into by a subsidiary). Here, J&J acted maliciously by directing Ethicon to terminate on an knowing pretextual “for cause” basis, to keep ChemImage from partnering with a competitor.

³⁸⁵ *See* FOF *supra* Section VIII(B); PX-753 at 1 (Jan. 6, 2023 Slack messages between F. Fernandez and M. Stuckley); PX-754 at 2 (Jan. 13, 2023 email from T. Lanier writing that J&J sought to “[a]ccelerate internalization of Erie Program to more closely align overall program spend in 2023 to the key priorities of funding Jupiter/Athena.”).

³⁸⁶ PX-495 (Mar. 18, 2024 article, “Johnson & Johnson MedTech working with NVIDIA to scale AI for surgery”).

³⁸⁷ *Id.*

³⁸⁸ *See* FOF *supra* Section VIII.

³⁸⁹ *See* H. Abouhalka Dep. Tr. at 9:21-10:4, 21:14-22:6 (admitting work on an internal critical structure detection program); T. Lanier Dep. Tr. at 54:17-18 (same).

And J&J cannot rely on the “economic interest” defense as an affirmative defense to the tortious interference claim. “The defense of economic interest does not apply... where the allegedly interfering part[y] acted to protect their own interest instead of their interest in the breaching party’s business.” *VR Optics, LLC v. Peloton Interactive, Inc.*, 2017 WL 3600427, at *5 (S.D.N.Y. Aug. 18, 2017); *see also Horowitz v. Nat’l Gas & Elec., LLC*, 2018 WL 4572244, at *6 (S.D.N.Y. Sept. 24, 2018) (rejecting economic interest defense where plaintiff did not allege that third party’s interference with contract “was for anyone’s benefit other than” that of the third party). The record at trial will establish that J&J’s interference was done for its own benefit, rather than out of any economic concern for its subsidiary, Ethicon.³⁹⁰ The economic interest defense also fails where the interfering party acted with malice, as J&J did here. *Kargo, Inc. v. Pegaso PCS, S.A. de C.V.*, 2008 WL 2930546, at *10 (S.D.N.Y. July 29, 2008) (economic interest defense may be rebutted upon “a showing either of malice on the one hand, or fraudulent or illegal means on the other”). Malice in the legal sense is ascribed a “liberal meaning” and includes “the intentional doing of a wrongful act without legal justification.” *Georgitsi Realty, LLC v. Penn-Star Ins.*, 702 F.3d 152, 156 (2d Cir. 2012).

Accordingly, the third element of the tortious interference with contract claim is met. *See Albany Molecular Rsch., Inc. v. Schloemer*, 2010 WL 5168890, at *6 (N.D.N.Y. Dec. 14, 2010) (upholding tortious interference with contract claim where the third party acted “in furtherance of [its own] interests, with knowledge of the [] contract and with the intent to induce [Plaintiff] to breach that contract”).

D. Ethicon Breached The Agreement

³⁹⁰ *See FOF supra* Section VIII.

Fourth, as explained in greater detail *supra* at Sections I-II, Ethicon ultimately breached the Agreement, when it purported to terminate “for cause” on March 6, 2023, and later declared the termination effective on April 26, 2023.³⁹¹ *See David Goldreyer, Ltd. v. Van de Wetering*, 630 N.Y.S.2d 18, 24 (1st Dep’t 1995) (tortious interference claim permitted where third party “was induced to breach the Mutual Receipt Agreement”).

The evidence at trial will also demonstrate that J&J’s conduct was the “but for” cause of Ethicon’s breach. “The inducement causing the breach ‘may be any conduct conveying to the third person the actor’s desire to influence him not to deal with the other[.]’” *St. John’s Univ., New York v. Bolton*, 757 F. Supp. 2d 144, 173 (E.D.N.Y. 2010) (quoting Restatement (Second) of Torts § 766 cmt. K). As the record will show, had J&J not approved the decision to terminate, Ethicon would not have breached the Agreement. The fourth element is met.

E. ChemImage Was Damaged

Finally, uncontroverted evidence demonstrates that ChemImage sustained damages from the termination of the Agreement, as explained in the following Section. Unlike contract damages, “[d]amages for tortious interference can include (a) the pecuniary loss of the benefits of the contract ... ; (b) consequential losses for which the interference is the legal cause; and (c) emotional distress or actual harm to reputation, if they are reasonably to be expected to result from the interference.” *AP Links, LLC v. Russ*, 2017 WL 3394599, at *8 (E.D.N.Y. Aug. 7, 2017) (quoting *Int’l Mins. and Res., S.A. v. Pappas*, 96 F. 3d 586, 597 (2d Cir. 1996)) (cleaned up).

IV. CHEMIMAGE’S DAMAGES

For a breach of contract claim in New York “it is well established that the non-breaching party may recover ‘general damages which are the natural and probable consequence of the

³⁹¹ *See Proposed Conclusions of Law supra* Sections I–II (“COL”).

breach.” *Moreno-Godoy v. Kartagener*, 7 F.4th 78, 85 (2d Cir. 2021) (quoting *Kenford Co. v. Cty. of Erie*, 73 N.Y.2d 312, 319 (N.Y. 1989)). “These direct damages are usually expectation damages, measured by what it would take to put the non-breaching party in the same position that it would be in had the breaching party performed as promised under the contract.” *Id.* (citations omitted). “Where a breach of contract causes a plaintiff to lose an income-producing asset and that asset “has a determinable market value, a plaintiff may seek to recover that value whether the asset is tangible or intangible property or almost any kind of contract right.” *Safka Holdings LLC v. iPlay, Inc.*, 42 F. Supp. 3d 488, 493 (S.D.N.Y. 2013) (quoting *Schonfeld v. Hilliard*, 218 F.3d 164, 177 (2d Cir. 2000)). ChemImage is entitled to these damages whether it proves breach of contract, tortious interference, or both. *See, e.g., Int’l Mins.*, 96 F.3d at 597 (“It is well-settled that, under New York law, a plaintiff in a tortious interference with contract case is entitled to damages in the amount of the full pecuniary loss of the benefits of the contract[.]”).

A. Damages for Failure to Pay Termination Fee

Under Agreement Section 10.4.1(a), Ethicon agreed to pay ChemImage \$40 million upon its termination of the Agreement without cause. By improperly terminating the Agreement “for cause” when no cause existed, failing to follow the contractually-mandated process for termination, and failing to honor the Agreement’s notice and cure provisions, Ethicon deprived ChemImage of the agreed-upon termination fee. The Court has already found that, if it can establish breach, ChemImage is entitled to no less than the \$40 million termination fee that was improperly withheld.³⁹² ChemImage’s damages for Ethicon’s failure to pay the termination fee

³⁹² Dkt. 64 at 12.

are \$46.87 million, consisting of the \$40 million termination fee plus nine percent prejudgment interest from March 6, 2023 (the breach date) through January 31, 2025.³⁹³

B. Damages For IP Impairment

Ethicon’s purported “for cause” termination also deprived ChemImage of rights to ChemImage’s core technology. Under the Agreement, ChemImage licensed to Ethicon all ChemImage IP developed before or independent of the Agreement with applications directed to surgical detection, visualization, and identification of anatomic structures, as well as tumor detection.³⁹⁴ This technology, along with related tangible assets, know-how, and business processes, was the foundation of ChemImage’s business.³⁹⁵ The Court previously found that, if it can prove a breach, ChemImage “may well be” entitled to damages “‘far in excess of \$40 million’ because, ‘[w]ithout the \$40 million and unimpeded rights to its core intellectual property, ChemImage lost the full value of its technology’ and ‘eventually close[d] its doors.’”³⁹⁶ The record at trial will show that this is precisely what occurred.

Had Ethicon terminated the Agreement without cause, ChemImage would have had unencumbered rights to the CI Core IP, as well as a non-exclusive license to certain IP developed under the Agreement.³⁹⁷ But because Ethicon wrongfully terminated the Agreement “for cause,” the CI Core IP remained subject to an exclusive license to Ethicon, which prevented ChemImage from monetizing its technology or partnering with another firm to continue its development.³⁹⁸

³⁹³ See D. Plastino Aff. ¶ 75; N.Y. C.P.L.R. 5004.

³⁹⁴ See Agreement §§ 1 (“CI Core IP” and “CI Developed Lightsphere IP” definitions); 4.1.1; 4.1.2.

³⁹⁵ J. Cohen Aff. ¶ 63.

³⁹⁶ Dkt. 64 at 12.

³⁹⁷ See Agreement §§ 1 (“CI Core IP” definition), 9.1, 10.4.4(a).

³⁹⁸ See Agreement § 10.3.3; J. Cohen Aff. ¶ _.

This resulted in ChemImage ceasing operations, terminating its employees, and liquidating its assets.³⁹⁹

Experts for both parties agreed that, had Ethicon terminated the Agreement without cause and unencumbered rights to the CI Core IP reverted to ChemImage, the best use of those rights was to collaborate with a new partner to continue developing ChemImage's technology.⁴⁰⁰ Using an industry leading Discounted Cash Flow method, David Plastino, a valuation expert with decades of experience valuing companies and IP assets, valued the portfolio of assets related to ChemImage's medical imaging technology at \$109.47 million as of the breach date, March 6, 2023.⁴⁰¹

Mr. Plastino's valuation captures the value ChemImage could reasonably have expected to realize from an alternative partnership to develop the CI Core IP had Ethicon properly terminated the Agreement without cause.⁴⁰² However, as a direct and foreseeable result of Ethicon's breach and improper retention of exclusive rights to the Core ChemImage IP, ChemImage lost the economic benefit of this alternative partnership and its medical imaging assets entirely.⁴⁰³ Including statutory prejudgment interest from the breach date to January 31, 2025, damages for Ethicon's impairment of ChemImage's assets are approximately \$124.47 million.⁴⁰⁴

Combined with the damages for Ethicon's failure to pay the termination fee, ChemImage's damages due to Ethicon's breach total \$171.34 million, inclusive of statutory interest.

³⁹⁹ See J. Cohen Aff. ¶¶ 58, 61.

⁴⁰⁰ D. Plastino Aff. ¶ 61; *see also* J. Donohue Dep., Tr. 265:25-266:12.

⁴⁰¹ D. Plastino Aff. ¶ 4.

⁴⁰² D. Plastino Aff. ¶ 106.

⁴⁰³ D. Plastino Aff. ¶ 62.

⁴⁰⁴ D. Plastino Aff. ¶ 75; N.Y. C.P.L.R. 5004.

C. Additional Relief

Pursuant to Appendix C of the Agreement, ChemImage is entitled to its attorneys' fees and expenses. As of January 30, 2025, ChemImage's attorneys' fees and expenses are approximately \$7.86 million.⁴⁰⁵ ChemImage is also entitled to a Declaration that Ethicon's exclusive license to the Core ChemImage IP is null and void, and that ChemImage is entitled to a non-exclusive license to IP jointly developed pursuant to the Agreement and IP developed by ChemImage pursuant to the Agreement that can be used for surgical detection, visualization, and identification of anatomic structures, as was contemplated by the Agreement in the event of a "without cause" termination.⁴⁰⁶

Under New York law, "when a contract provides that in the event of litigation the losing party will pay the attorneys' fees of the prevailing party, the court will order the losing party to pay whatever amounts have been expended by the prevailing party, so long as those amounts are not unreasonable." *Diamond D Enterprises USA, Inc. v. Steinsvaag*, 979 F.2d 14, 19 (2d Cir. 1992) (citation omitted); *see also KLS Diversified Master Fund, L.P. v. McDevitt*, 532 F. Supp. 3d 126, 139 (S.D.N.Y. 2021), *aff'd*, 2022 WL 2759055 (2d Cir. July 13, 2022) ("when a contract provides that in the event of litigation the losing party will pay the attorney' fees of the prevailing party, the court will order the losing party to pay whatever amounts have been expended by the prevailing party, so long as those amounts are not unreasonable.").

Here, Ethicon agreed to pay ChemImage's "reasonable attorneys' fees and court costs as determined by the court hearing the Dispute."⁴⁰⁷ As of January 30, 2025, ChemImage's attorneys'

⁴⁰⁵ D. Plastino Aff. ¶ 4. ChemImage respectfully requests the opportunity to submit a declaration after trial with an updated attorneys' fees calculation.

⁴⁰⁶ Agreement § 10.4.4(a).

⁴⁰⁷ *See* Agreement, Appendix C.

fees⁴⁰⁸ are approximately \$21,642,702.97, which includes a 3x lodestar on Quinn Emanuel’s fees, and its costs and expenses are approximately \$2,886,704.02. In complex cases, such as this, courts routinely award lodestar multiples of greater than three. *See, e.g., Wal-Mart Stores, Inc. v. Visa U.S.A., Inc.*, 396 F.3d 96, 123 (2d Cir. 2005) (affirming multiple of 3.5 as reasonable); *In re Payment Card Interchange Fee & Merchant Discount Antitrust Litig.*, 991 F. Supp. 2d 437, 447-48 (E.D.N.Y. Jan. 10, 2014) (awarding lodestar of 3.41, which was “comparable to multipliers in other large, complex cases”); *In re Telik, Inc. Sec. Litig.*, 576 F. Supp. 2d 570, 590 (S.D.N.Y. 2008) (“In contingent litigation, lodestar multiples of over 4 are routinely awarded by courts, including this Court.”); *Lopez v. Fashion Nova*, 2021 WL 4896288, at *3 (S.D.N.Y. Oct. 19, 2021) (“In this Circuit, “[c]ourts regularly award lodestar multipliers of up to eight times the lodestar, and in some cases, even higher multipliers.”); *Davis v. JP Morgan Chase & Co.*, 827 F. Supp. 2d 172, 185 (W.D.N.Y. 2011) (awarding lodestar multiplier of 5.3, which while “toward the high end,” was “not atypical for similar fee-award cases”).

Further, because of the qualifications of Quinn Emanuel’s attorneys and the award-winning, high-level quality of its representation, courts have repeatedly and consistently held that Quinn Emanuel’s rates are reasonable. *See, e.g., Clark v. Castor and Pollux Ltd. Liability Co.*, 2019 WL 4467117, at *19 (N.Y. Cnty. Sup. Ct. 2019) (noting that plaintiff “was fortunate to obtain the capable assistance of Quinn Emanuel, ‘one of the top litigation firms in the country,’ whose ‘experience, reputation, and ability’ are widely regarded as ‘outstanding,’” and that “Quinn Emanuel’s rates are reasonable for a firm of its stature and comparable to those charged by other leading firms.”); *In re Dell Techs. Inc. Class V S’holders Litig.*, 300 A.3d 679, 726-28 (Del. Ch.

⁴⁰⁸ D. Plastino Aff. ¶ 4. ChemImage respectfully requests the opportunity to submit a declaration after trial with an updated attorneys’ fees calculation.

2023) (granting Quinn Emanuel an incentive award after it and its co-counsel secured a record-breaking \$1 billion settlement for a stockholder class after conducting a lodestar “cross-check” and noting that “a top-tier firm makes a difference for case outcomes in Chancery M&A litigation” that is “obvious to a regular observer”), *aff’d*, 326 A.3d 686 (Del. Aug. 14, 2024); *Rudi v. Wexner*, No. 2:20-cv-3068 (MHW), 2022 WL 1682297, at *5 (S.D. Ohio May 16, 2022) (“The Court finds that [Quinn Emanuel’s] hourly rates are reasonable under the circumstances of this particular [contingency] case. Accordingly, this factor weighs in favor of granting the requested fee.”); *Blattman v. Siebel*, No. 15-cv-530 (CFC) (D. Del. Dec. 6, 2021) (ECF No. 434) (finding attorneys’ fees requested by Quinn Emanuel reasonable and declining to reduce the fee award by the requested percentage); *Proofpoint, Inc. v. Vade Secure, Inc.*, No. 3:19-cv-4238 (MMC) (RMI) (N.D. Cal. Dec. 17, 2020) (ECF No. 376 at 7) (finding that Quinn Emanuel attorneys “are experienced and seasoned practitioners; that they are employed at a large international firm with a highly regarded reputation; that they have highly specialized ... backgrounds” and that the firm’s fees are reasonable); *Liqwd, Inc. v. L’Oréal USA, Inc.*, 17-cv-14 (JFB) (SRF) (D. Del. Dec. 16, 2019) (ECF No. 1162 at 25-28) (finding that Quinn Emanuel’s “hourly rates and [] hours spent [are] reasonable”).

In addition to its attorneys’ fees and expenses, ChemImage is entitled to a Declaration that Ethicon’s exclusive license to the Core ChemImage IP is null and void, and that ChemImage is entitled to a non-exclusive license to IP jointly developed pursuant to the Agreement and IP developed by ChemImage pursuant to the Agreement that can be used for surgical detection, visualization, and identification of anatomic structures, as was contemplated by the Agreement in the event of a “without cause” termination.⁴⁰⁹

⁴⁰⁹ Agreement § 10.4.4(a).


CONCLUSION

For the foregoing reasons, the Court should enter judgment in ChemImage's favor.

Dated: New York, New York
January 30, 2025

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

By: _____


Andrew J. Rossman
Alex Spiro
Courtney C. Whang
Ron Hagiz
295 Fifth Avenue
New York, New York 10016
Telephone: (212) 849-7000
Fax: (212) 849-7100
andrewrossman@quinnemanuel.com
alexspiro@quinnemanuel.com
courtneywhang@quinnemanuel.com
ronhagiz@quinnemanuel.com

James Bieber
865 S Figueroa Street, 10th Floor
Los Angeles, California 90017
Telephone: (213) 443 3000
Fax: (213) 443-3100
jimmybieber@quinnemanuel.com

Attorneys for Plaintiff